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| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 3-01 | | | |
| | | | | | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | |
| Contract Number EP-C-16-011 | | | Contract Period 11/01/2016 To 06/30/2020 Base Option Period Number 3 | | | Title of Work Assignment/SF Site Name Pathogens, QMRA, fecal sources | | | |
| Contractor ICF Incorporated, L.L.C. | | | | Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6, 3.8 | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 07/01/2019 To 06/30/2020 | | | |
| Comments: | | | | | | | | | |
| <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund | | | | | | | | | |
| SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) (Cents) | Site/Project (Max 8) | Cost Org/Code |
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| Contractor WP Dated: | | | | Cost/Fee | | LOE: | | | |
| Cumulative Approved: | | | | Cost/Fee | | LOE: | | | |
| Work Assignment Manager Name John Ravenscroft <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: | | | |
| | | | | | | Phone Number: 202-566-1101 | | | |
| | | | | | | FAX Number: | | | |
| Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: | | | |
| | | | | | | Phone Number: 202-566-1107 | | | |
| | | | | | | FAX Number: | | | |
| Other Agency Official Name Shirley Harrison <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: | | | |
| | | | | | | Phone Number: 202-566-1107 | | | |
| | | | | | | FAX Number: | | | |
| Contracting Official Name Kathleen Rechenberg <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: | | | |
| | | | | | | Phone Number: 513-487-2853 | | | |
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**PERFORMANCE WORK STATEMENT
ICF CONTRACT # EP-C-16-011
WORK ASSIGNMENT #3-01**

Title: Activities to Support Understanding Health Risks from Exposure to Pathogens in Water

Work Assignment Contracting Officer's Representative (WACOR):

John Ravenscroft (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Alternate WACOR:

Sharon Nappier (Mail Code 4304T)
Telephone #: 202-566-0740
E-mail: nappier.sharon@epa.gov

Contract PWS: 3.1, 3.3, 3.6, 3.8

Period of Performance: July 1, 2019 through June 30, 2020

****Note:** No confidential business information (CBI) data will be needed during conduct of this work assignment.

Background

The Environmental Protection Agency (EPA) is interested in understanding the links between the source(s) of pathogens (e.g., the nature and magnitude of fecal loadings to surface waters), how the sources of pathogens affect the pathogen profile reaching waterbodies, the relationships between pathogen profiles and the surrogates used to gauge waters quality, and the parameters considered to estimate exposure. While the studies used to inform previous criteria recommendations have been conducted in waters impacted by human sources of contamination under dry weather or base flow conditions, EPA would like to better understand the risks associated with other fecal sources and wet weather impacts to surface waters. Quantitative Microbial Risk Assessment (QMRA) has been identified as a tool that the Agency can use to complement existing epidemiological and other health data and better understand the relative risks associated with other sources of surface water contamination. The Agency's previously supported QMRA efforts have indicated that there are potentially significant differences in health risks associated with different sources of fecal contamination. This work assignment covers various aspects of further development and application of QMRA in support of criteria development and implementation. This work assignment also includes the consideration of other types of health study information, such as epidemiological results, to provide an increased understanding of the potential health effects from exposure to pathogens in water.

Goals and Objectives

The overall objective of the tasks in this work assignment is to inform the Agency on the human health risks associated with exposure to pathogens in water. Specific goals are:

- a. Provide decision-makers an improved understanding of pathogen-associated risks in ambient and drinking waters, utilize results from existing health studies (e.g., epidemiological, quantitative microbial risk assessment (QMRA), illness outbreak reports, etc.), provide risk information on waters where epidemiology data or other health studies are currently lacking.
- b. Refine the Agency's understanding of the risk differences that exist for different fecal contamination sources and how those risks relate to the observed health risks reported by epidemiological studies conducted in fecal pollution-impacted waters.
- c. Further refine the Agency's understanding of the human health risks from exposure to waters affected by wet weather-associated loadings of pathogens.
- d. Aid the Agency in understanding how different exposure profiles (e.g., life stage-specific, drinking water, and recreational water) can affect human health risks.
- e. Inform the Agency on inclusion of multiple water quality measures in a matrix (e.g., a 'toolbox') to help identify hazardous conditions and inform decision-making.

Quality Assurance:

The tasks (Tasks 2 and 4) in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the approved ICF March 2017 Programmatic QAPP (pQAPP) to assure the quality of the data used under this work assignment. The scope of the March 2017 pQAPP covers secondary data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved pQAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the QA/QC procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

Tasks

Task 1: Work plan, monthly progress reports and quality assurance

Task 1.1. Work plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs

greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task 1.2. Monthly Progress Reports

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task Area 1.3. Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines (www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information) and shall complete the complete OW IQG Checklist as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this work assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

Task Area 2: General Project Support

EPA is interested in furthering the development of the QMRA process for criteria implementation and as a process for water quality management for various waterbodies. There are numerous varied tasks within this QMRA-related work assignment. The various tasks in this work assignment necessitate a comprehensive overview and planning process for the work assignment goals to be realized. The scope of this task falls into two main areas: project management support and project communication support.

Task 2.1: Project planning and management

The contractor shall conduct project strategic planning in conjunction with the WACOR. The purpose of this subtask will be to develop a comprehensive plan that includes all related tasks and deliverables in the context of the Agency timeline for completing tasks within this work assignment, such as publishing Recreational water criteria and implementation guidance. For each task area, the contractor shall work with the WACOR to develop a project plan, including scope, goals, and timelines.

This task will require contractor travel to EPA for an initial planning meeting and quarterly update meetings (at a minimum) thereafter during the period of performance of this work assignment. Contractor travel for planning and update meetings are within the DC local commuting area. The contractor shall provide personnel knowledgeable in technical areas (e.g.,

QMRA, microbial ecology, public health, and epidemiology) and project planning and management for this process. Expertise in Microsoft Project is preferred. The initial meeting for each task area is crucial to the entire overall work assignment and therefore will need to occur as one of the first steps after work has begun on this work assignment.

Deliverables under this subtask will include a Gantt chart timeline listing all related tasks with interim and final deliverable dates and quarterly project updates delineated. As part of the deliverables under this subtask, the contractor shall include a discussion on the Agency's project goals and objectives and how each of the tasks supports them. It is hoped that this exercise will also help to identify any gaps that will need to be addressed prior to the publication of deliverables.

Task 2.2: Project communication support:

EPA needs to communicate its efforts to a broad audience. From engaging other scientists on technical issues to discussing regulatory actions with stakeholders and the public, EPA needs to be keenly aware of effective communication strategies. For all tasks under this work assignment, the contractor shall discuss with the WACOR ways to achieve effective communication objectives. The audience for specific deliverables may be different even though the analytical approach may be similar. Questions to cover with the WACOR should address the audience and purpose of the deliverable, ideas for finding effective presentation strategies, suggestions for achieving the communication objectives given differing formats (e.g., written versus oral). The contractor shall, based on technical direction given by the WACOR, provide support in preparing interim project updates and other materials for internal and external audiences. These may include but are not limited to short briefing documents and PowerPoint presentations. The contractor may also be requested to participate in and/or conduct briefings and meetings. The contractor may also be requested to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The contractor shall coordinate with the WACOR for the proper timing and need for these activities. A weekly update call with the WACOR will be required for this task, as needed.

Work under meeting-related activities and travel-related expenses shall not occur until approval is obtained and provided by the CL-COR.

Task 2.3: Development of Technical Support Documents

EPA has been developing technical support documents to help state and local agencies implement criteria recommendations. These documents also aid others in EPA to evaluate standard package submissions that may contain technical differences compared to EPA recommendations.

EPA developed two documents that have been internally and externally peer reviewed and have gone through two steps of management review. The contractor shall support the WACOR with comment response, document revision and finalization of the document for publication by EPA. The two documents are: 1) Site-Specific Alternative Recreational Criteria Technical Support Materials for Alternative Health Relationships, and 2) Site-Specific Alternative Recreational Criteria Technical Support Materials for Predominantly Non-Human Fecal Sources. These documents shall be revised in response to final management comments and finalized for

publication clearance. During the previous option year, the document “Site-Specific Alternative Recreational Criteria Technical Support Materials for Alternative Health Relationships” was revised to reflect management comments and submitted for clearance. For both documents, communication materials (e.g., fact sheets, management briefings, etc.) shall be prepared to support the finalization. Additional comments from Agency management may need to be incorporated prior to finalizing the documents. The contractor shall discuss with the WACOR, the specific communication strategy for each document to determine what specific materials will be needed.

Task 3: *Characterization of Human Health Risks from Exposure to Pathogens in Water*

This task area is to support EPA with collating, developing and interpreting health study information that characterizes the human health effects from exposure to pathogens in water. Because microbial and chemical surrogates are used to routinely gauge water quality and estimate the potential for risk, the contractor shall consider how the surrogates relate to the pathogen profile and the effectiveness of various surrogates for predicting the hazardous condition. This task includes the evaluation and interpretation of different types of health study information (e.g., epidemiological, QMRA, clinical, outbreak information, etc.) to provide context for criteria development (or other regulatory-related) activities and for decision-makers. Specific tasks are listed below, but additional tasks may be needed due to the iterative nature of risk assessment and the risk management questions being addressed.

Task 3.1: Systematic Literature Searches

The contractor shall support EPA with the conduct of systematic literature searches and retrieval of information from the scientific literature on topic relevant to the task areas in this work assignment. HECD has been developing a SOP for systematic literature review that the contractor shall utilize for this purpose. Before any searching and collation of information is conducted, the contractor shall discuss with the WACOR the purpose and scope of the search, including search terms; the strategy for screening the search results, including a rationale for identifying information used and not used; and, for substantiating data quality for items used in deliverables.

Task 3.2: Marion et al. study

Another epidemiology study was published in 2010 that examined a small inland lake in Ohio affected by point and non-point human sources (Marion et al, 2010). This small-scale study also used fecal indicator bacteria cultural methods to estimate water quality. EPA is already using this water quality data in efforts for comparing various enumeration methods. The availability of this data would also serve useful to demonstrate the applicability of the previous developed QMRA models to a human impacted freshwater inland lake. In addition to evaluating the epi data as with the other anchoring efforts, the contractor shall replicate EPA’s previous efforts with reverse QMRA anchoring efforts in coastal freshwaters using the data from this small-scale epi study. The contractor shall also evaluate the application of the QMRA process at such a small waterbody (i.e., given the potential longer-term goals of applying QMRA in estimating risk in a specific type of waterbody affected by a specific source, the contractor shall use this exercise to evaluate the application of the QMRA process in this context). The contractor shall evaluate watershed information for fecal sources potentially affecting the study location. The goal of this task is to produce a risk-based evaluation of the water quality extant at the study location. The

deliverable for this task will be a report suitable for publication in a peer-reviewed science journal. HECD management provided comments on the manuscript late in the previous option year. The contractor shall aid in addressing the comments.

Task 3.3: Boquerón

EPA conducted two parallel efforts in Boquerón, Puerto Rico during the summer of 2009. One effort was a full-scale epidemiology study and the second was a significant water quality monitoring effort that included the enumeration of pathogens and fecal indicator organisms at the beach and at the potential sources affecting the beach. EPA has conducted additional analyses to better understand potential risks from the various fecal sources affecting the beach. The contractor shall utilize the data from these efforts to further refine the analysis to improve the understanding of recreator risks and to help with identifying the hazardous condition. The contractor shall coordinate with the Office of Research and Development in using the epidemiology data.

Additional questions to address in this QMRA include:

What do the epi and monitoring data, as well as the risk assessment results, suggest about the potential fecal sources affecting the Boquerón beach?

Given the level of pathogens detected during the monitoring, what levels would have been needed (e.g., enteric viruses) in order for this beach to show a similar health relationship to fecal indicators as studies conducted at other marine beaches?

Do the results suggest that population immunity was a confounding factor in the epi study (i.e., can the risk assessment health modeling examine such potential background immunity in a sensitivity analysis)?

Task 3.4: QMRA to improve the understanding of risks related to exposure

Communication of swimming-associated risks in recreational waters affected by fecal contamination can be confusing. Risk estimates are based on health studies conducted at a small number of beach sites, representative of a very narrow fecal contamination scenario, and are then generalized to the broader set of waters with the recreation designated use. Numerous studies have demonstrated that the level of water quality recommended by EPA's recreational water quality criteria can correspond to markedly different risk profiles. Of particular concern, human sources of fecal contamination can pose the highest relative risk levels; however, risk managers have been slow to incorporate this information and instead rely on a 'one size fits all' approach that assumes all recreational waters are just like those that are characterized during empirically-based health studies conducted at a few discrete locations. This approach can translate into significant under-protection of human health in some types of waters and can lead to possible misinterpretations of what risks really mean and 'safe to swim' decisions.

This task includes the development of exposure profiles for specific exposure routes of pathogens in water (e.g., drinking, recreational). The profiles may be for specific life stages or be representative of the populations included in empirical studies. The contractor shall utilize EPA's *Exposure Factors Handbook* and other information to inform the development of the profiles.

QMRA can be used to evaluate the risks associated with the exposure profiles and include a characterization of risks from different activities, different pathogen profiles, and different life stages. This task will integrate those various parameters and factors into a methodical framework to assess risk and inform decision-making.

Task 3.5: Understanding risks associated with wet weather impacts on water quality

Most of the health information available was developed under dry weather or base flow conditions. Very few health studies have characterized wet-weather-associated health effects specifically as part of the study design. The surrogates used to evaluate water quality increase substantially following wet weather, but there doesn't appear to be a concomitant increase in pathogen-related risks. Health study information suggests that wet weather-associated pathogen risks can be lower at substantially higher levels of indicator. The purpose of this task is to design an analysis to help inform the discussion at EPA on how to consider the impacts of wet weather on pathogen-related risks.

This task will involve: searching the literature (see Task 3.1), constructing hazard profiles for both dry and wet weather events, evaluating exposure related to wet weather, consideration of water quality metrics that may differ from those traditionally used, and estimating human health risks, including a relative understanding of risks under different conditions. The contractor shall conduct project planning with the WACOR.

Task 3.6: Understanding water quality metrics, how they relate to risk, and the 'toolbox'

The traditional approach with measuring water quality and assessing the potential for pathogen-related risks is to utilize a very limited number of culture-enumerated fecal indicator bacteria. These bacteria may function as good surrogates under certain conditions, but are inadequate under other conditions. The science related to alternative water quality metrics, including other indicator organisms, source-specific surrogates, direct detection of pathogens and the application of other enumeration methodologies, has progressed substantially over the last 35 years. To date, this information has not been included into the regulatory framework despite numerous examples around the country where this additional information has been used to inform decision-making and improve public health protection.

The purpose of this task is to systematically evaluate the state of the science related to water quality metrics used to measure water quality for estimating the potential risks from pathogens. The goal of this task is to develop a 'toolbox' of metrics that can be used by EPA, states, and others that consists of multiple water quality metrics that can be utilized based on a number of factors to provide improved assessments and better inform decisions.

This task may involve literature searches and the development of reports that cover the various metrics available, conditions that may support or preclude their use, methodological approaches, and interpretation of results in context with EPA recommendations. The contractor shall conduct project planning with the WACOR.

Based on available information, QMRA may be used to estimate levels of various water quality metrics at discrete levels of protection.

Task 3.7: Understanding and interpreting health study results from different types of studies and experimental designs.

EPA considers a range of different types of health studies as it collates, evaluates and discusses the state of the science used to inform decision-making. The various health studies examined are often conducted under a range of conditions, potentially represent different relationships between health and water quality metrics, and the results suggest that their interpretation and application should be considered in context with other studies. EPA is interested in examining how to compare health study results; potentially using a level of health protection as a pivot point to connect study results generated by different methodological approaches. Using QMRA analyses to compare the exposure profiles characterized in different study types could also provide needed context for the Agency.

The contractor shall conduct the following activities:

- a) Evaluate a cut-point analysis approach using indicator data associated with health effects (e.g., enterococcus qPCR and NGI) to characterize potential levels of water quality indicative of significant increases in health risks.
- b) Evaluate available health study information for the potential health burden experienced by children. Use QMRA to characterize empirical epidemiological results.
- c) Coordinate with the investigators on an RCT study to obtain the raw data from that study and re-analyze the results using the statistical methods employed by Wade and colleagues for the NEEAR studies. This analysis will provide an indication of whether or not results from RCTs and PCs can be compared directly and will help to answer the question of whether the differences observed in existing epidemiology studies are due to the study design or other factors.
- d) Use a QMRA framework to translate results from an RCT to one that is comparable to a PC study. Conduct sensitivity analyses to identify the model parameters that most strongly influence the results. Compare the results with those from (a) above if RCT data is available.
- e) If the sensitivity analyses indicate that the volume of water ingested is a critical component, conduct a screening-level analysis using the exposure protocol specified by the RCT epidemiology studies. This study will determine if the volume of water ingested during the RCT epidemiology studies are likely to differ substantially from those that are generally used to characterize exposure volumes.
- f) Extend the work reported by Boehm (2007) using culturable and molecular methods for the indicators of highest interest in several disparate recreational

waterbody types of interest. This information would help to characterize the extent to which the method of allocating exposure to the subjects influences the results. If the density of indicators is highly variable in short spatial and temporal frames, differences in exposure sampling prescribed for RCT versus PC based epidemiological studies will not have a large influence on study results.

- g) Report findings to EPA in a memorandum, including potential next steps for this analysis.

General Requirements of the Work Assignment and Schedule

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be issued via written technical direction from the EPA WACOR.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.

Final Documents: The contractor shall submit final documents both electronically and in hardcopy to the WACOR.

Milestones and deliverables

| Milestone | Task | Due Date |
|--|-------------|--|
| Task 1: Work plan, monthly progress reports and quality assurance | | |
| Workplan | 1.1 | Per Contract Requirements |
| Development of contract level QAPP for Secondary Data | 1.3 | Within 20 calendar days of receipt of work assignment |
| Revised contract level QAPP for Secondary Data based on EPA comments | 1.3 | Within 20 calendar days of receipt of EPA comments |
| Task 2: General Project Support | | |
| Project Planning and Management | 2.1 | Initial planning meeting to be held within 10 calendar days of receipt of work assignment. Final project Gantt chart, goals and objectives statement, and gap analysis due within 2 weeks of initial meeting. Planning meetings to be held roughly every quarter thereafter. |

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| Project Communications Support | 2.2 | After workplan approval, throughout the period of performance. Other communication materials will be dependent on the analytical results. |
| Development of Technical Support Documents | 2.3 | After workplan approval, the contractor shall meet with the WACOR within 10 days to discuss comment response and revisions. A timeline shall be developed for each document at that meeting. |
| Task 3: Characterization of Human Health Risks from Exposure to Pathogens in Water | | |
| Systematic Literature Searches | 3.1 | After workplan approval, throughout the period of performance for topics in received via technical direction. |
| Marion anchoring QMRA | 3.2 | After workplan approval, response to management comments within 4 weeks. |
| Boqueron QMRA | 3.3 | After workplan approval, subtask meeting within 20 days to discuss methodological approaches. |
| QMRA to improve the understanding of risks related to exposure | 3.4 | After workplan approval, subtask meeting within 20 days to discuss scoping and analytical approach. |
| Understanding risks associated with wet weather impacts on water quality | 3.5 | After workplan approval, project planning meeting within 20 days to discuss scoping and analytical approach. |
| Understanding water quality metrics, how they relate to risk, and the 'toolbox' | 3.6 | After workplan approval, project planning meeting within 20 days to discuss scoping and analytical approach. |
| Understanding and interpreting health study results from different types of studies and experimental designs. | 3.7 | After workplan approval, project planning meeting within 20 days to discuss scoping and analytical approach. |

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| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 3-02 | | | |
| | | | | | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | |
| Contract Number EP-C-16-011 | | Contract Period 11/01/2016 To 06/30/2020 Base Option Period Number 3 | | Title of Work Assignment/SF Site Name Children's risks from microbia | | | | | |
| Contractor ICF Incorporated, L.L.C. | | | | Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6, 3.8 | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 07/01/2019 To 06/30/2020 | | | |
| Comments: | | | | | | | | | |
| <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund | | | | | | | | | |
| SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2) | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) (Cents) | Site/Project (Max 8) | Cost Org/Code |
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| Work Plan / Cost Estimate Approvals | | | | | | | | | |
| Contractor WP Dated: | | | | Cost/Fee | | LOE: | | | |
| Cumulative Approved: | | | | Cost/Fee | | LOE: | | | |
| Work Assignment Manager Name John Ravenscroft <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> (Signature) (Date) </div> | | | | | | Branch/Mail Code: Phone Number: 202-566-1101 FAX Number: | | | |
| Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> (Signature) (Date) </div> | | | | | | Branch/Mail Code: Phone Number: 202-566-1107 FAX Number: | | | |
| Other Agency Official Name Shirley Harrison <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> (Signature) (Date) </div> | | | | | | Branch/Mail Code: Phone Number: 202-566-1107 FAX Number: | | | |
| Contracting Official Name Kathleen Rechenberg <div style="display: flex; justify-content: space-between; border-top: 1px solid black; margin-top: 10px;"> (Signature) (Date) </div> | | | | | | Branch/Mail Code: Phone Number: 513-487-2853 FAX Number: | | | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT - EP-C-16-011
WORK ASSIGNMENT #3-02**

Title: Children's risks from microbial contamination in recreational water

Work Assignment Contracting Officer Representative (WACOR):

John Ravenscroft (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Alternate WACOR:

Shamima Akhter (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Science and Technology, Office of Water
1200 Pennsylvania Avenue, NW
Washington DC, 20460
Phone: 202-566-1341
E-mail: akhter.shamima@epa.gov

****Note: No CBI data will be needed in the course of this work assignment.**

Contractor SOW: 3.1, 3.3, 3.6, 3.8

Period of Performance: July 1, 2019 through June 30, 2020

Background:

A growing body of scientific knowledge has demonstrated that children may suffer disproportionately from environmental health risks and safety risks. These risks occur because 1) children's neurological, immunological, digestive, and other bodily systems are still developing; 2) children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; 4) children's size and weight may diminish their protection from standard safety features; and 5) children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves.

The importance of identifying and assessing risks to children was made in Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risk¹, which states:

¹ Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks.
http://yosemite.epa.gov/oceph/ochpweb.nsf/content/whatwe_executiv.htm

“to the extent permitted by law and appropriate, and consistent with the agency's mission, each Federal agency:

(a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.

1-102. Each independent regulatory agency is encouraged to participate in the implementation of this order and comply with its provisions.”

The U.S. Environmental Protection Agency (EPA)’s Policy on Evaluating Risks to Children² :

“considers the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision-making process, including the setting of standards to protect public health and the environment. To the degree permitted by available data in each case, the Agency will develop a separate assessment of risks to infants and children or state clearly why this is not done - for example, a demonstration that infants and children are not expected to be exposed to the stressor under examination.”

The US EPA’s Office of Children’s Health Protection³ conducts research and supports risk assessments to assess children’s risks and susceptibility to environmental contaminants (chemicals, toxins, air pollutants). However, it’s not clear the extent, to which, children suffer disproportionate exposures and health outcomes as a result of exposure to pathogens, or other microbial-related risks, found in recreational surface waters. Few epidemiological data and quantitative risk assessments have explored children’s risks from microbial contaminants found in water, limiting the ability to determine if children experience different responses to waterborne fecal indicators and pathogens, or develop illness rates as a result of recreational water contact in the United States. Risks in children have specifically not been explored separately, but they are included as part of the general populations in most epidemiological studies.

Under the auspices of the Clean Water Act (CWA), the Agency regulates recreational water, and sets numeric indicator bacteria criteria (*Escherichia coli*, Enterococci) in surface (ambient) waters used for the purpose of recreational water contact. EPA issued new CWA 304(a) recreational ambient water quality criteria in December 2012. The science underpinned the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA would like to better understand the risks posed to children associated with

² Policy on Evaluating Health Risks to Children. <http://www.epa.gov/osa/spc/pdfs/memohlth.pdf>

³ The Office of Children’s Health Protection.

http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm

recreational exposures. This work assignment covers efforts to develop and disseminate the current understanding in this area.

The overall purpose of this performance work statement (PWS) is to examine multiple lines of evidence, such as the Centers for Disease Control (CDC) Recreational Water Illness outbreak data, exposure studies, risk assessment analyses and epidemiological data, to evaluate the potential that children have disproportionate risks of waterborne illness from recreational water contact.

Objectives:

1. Produce a comprehensive report for internal EPA evaluation detailing the known health information for children's waterborne illnesses from recreational water exposure. The report shall demonstrate an evaluation of the scientific literature, risk analysis (e.g., QMRA) and observational results (e.g., National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) study reports).
2. Produce a draft and final report for external scientific peer review based on the information covered in objective 1.
3. Produce communications materials to accompany reports including: a 1 to 2 page nontechnical synopsis, a technical summary document written in non-academic style for a non-scientific audience, a 'questions and answers' (Q&As) document covering areas of potential inquiry from nontechnical and technical audiences (both internal and external), and others as determined by the WACOR via technical direction.

The contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of discipline discussed. The contractor shall also be proficient in R programming and other relevant statistical tools. The contractor shall have practical experience in environmental microbiology, epidemiology, and statistical methods and analysis and have advanced credentials in statistics or environmental engineering. The contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development. The contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

Quality Assurance:

The tasks (Tasks 2 -4) in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the approved ICF March 2017 Programmatic QAPP (pQAPP) to assure the quality of the data used under this work assignment. The scope of the March 2017 pQAPP covers secondary data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved pQAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the QA/QC procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

Tasks

The contractor shall provide technical support in the evaluation of children's risks from exposure to microbial contamination in recreational waters. The scope of this PWS will fall under the following tasks:

Task 1: Work Plan and monthly progress reports (MPR)

Task Area 1.1. Work Plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task Area 1.2. Monthly Progress Reports

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoiced LOE and costs delineated by the tasks in this WA. The contractor shall provide the WACOR with regular updates detailing progress.

As described in the Quality Assurance Section, the contractor must follow the ICF-submitted March 2017 pQAPP for the use of existing data and, if applicable, application of peer reviewed existing model. The monthly progress report shall indicate, in a separate QA section, whether significant project-specific QA issues have been identified and how they are being resolved.

Task Area 1.3. Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines (<https://www.epa.gov/quality/epa-information-quality-guidelines>) and shall complete the Checklist for Influential Information, as needed, for each deliverable from this work assignment. The WACOR

will provide this checklist to the contractor through written technical direction. The contractor shall have a teleconference with the WACOR before the initiation of Task 2 to discuss the Information Quality Guidelines and the contractor's role in completing the checklist. At the end of the work assignment, the contractor shall provide a memorandum describing how the planned product(s) developed for this work assignment meet with EPA's Checklist for Influential Information and documenting the quality assurance procedures that were used in developing the deliverables under this PWS.

Task Area 2: *Characterize children's health risks from microbial contaminants.*

Understanding children's risks and their life stage-specific exposure patterns has been an ongoing effort at EPA. The WACOR will provide the contractor with the background information that has already been collected in this area. The contractor shall use this information as a starting point to develop the project report. The contractor shall conduct literature searches for the years 2011 to the present in the area of children's exposure parameters and health effects children experience following exposure to microbial contamination in surface waters. References collected, but not used will also require proactive justification. The contractor shall leverage efforts under other work assignments under this contract, such as 2-03 (The development of cyanotoxin ambient water quality criteria), with this task as the criteria contains an assessment of children's exposure parameters. The contractor shall ensure that no duplication of effort occurs, such as searching the scientific literature or evaluating sensitive subpopulations.

For this task, the contractor shall characterize the biological, immunological (resistance, immunity), social and behavioral factors impacting children's risks from microbial contaminants in water. These contaminants can include infectious and pathogenic microorganisms, as well as, microbial constituent compounds (e.g., phycocyanins) or produced by microbes (e.g., cyanotoxins).

The contractor shall compile available data on waterborne organisms associated with recreational water illness (viruses, fungi, protozoa, bacteria) using published data. This effort includes extending or building upon compilations already conducted in HECD. The contractor shall create appropriate and effective graphics to identify organisms most frequently associated with adverse health effects in children vs. adults. Where possible, the contractor shall report frequency and occurrence data by regions or other delineation as specified by the WACOR through written technical direction. This task will provide a high-level summary of the burden of illness posed by waterborne pathogens.

The contractor shall evaluate the peer-reviewed and published literature including government publications and reports (e.g., EPA, CDC, USDA, FDA, and WHO) to characterize factors that impact children's response to infections or other health endpoints. The contractor shall address the following key points:

- 1) What are the biological processes/characteristics that differentiate children from adults related to waterborne infections and illnesses?
- 2) What immunological processes impact children's responses to waterborne infectious or other microorganisms?

- a. Explore the issues of resistance
- b. Self-limiting disease
- c. Immunity and age
- 3) Identify and review behavioral studies in the literature to identify behaviors in children that impact recreational water exposure to fecal contamination
 - a. Ingestion studies
 - b. Hand to mouth studies, and
 - c. Hand washing behavior

The contractor shall assess epidemiologic studies (EPA NEEAR cohort studies, other studies in the United States, cohort studies, as well as RCT/ randomized studies from international sites) to document human health endpoints from recreational water contact. The discussion should discuss key health endpoints in the study populations related to illness rates in children versus adults.

Specifically, for waterborne infectious pathogens, the contractor shall address the following key points:

- 1) Which microorganisms are known to cause the most frequent illnesses in children?
- 2) Are there specific sources of infection, transmission routes or infectious doses in recreational waters that have a differential effect on children?
- 3) Are there specific age groups of children that are susceptible to different pathogens?
- 4) Describe any evidence of illness severity or differences in severity between lifestages for specific pathogens or other microbial exposures. Evidence of severity such as hospitalization, transplants, and sequelae from recreational water.
- 5) Identify infection source, transmission routes, and infectious doses from recreational water.

The contractor shall compile available Centers for Disease Control and Prevention outbreak data on waterborne organisms associated with recreational water illness in ambient/surface waters and pools in the United States using published data. Other outbreak information available from the peer reviewed scientific literature shall be considered here too. The contractor shall create appropriate and effective graphics to identify organisms most frequently associated with children vs. adults, including organism type and water body/source.

The contractor shall address the following key points:

- 1) Identify the populations, venues/waterbody types (lakes, streams, ocean, rivers etc)
- 2) Provide descriptions on how children are categorized (age, ethnicity, gender)

- 3) Identify which subsets of children are most impacted by RWI, where possible
- 4) Identify risk factors for illness
- 5) Identify the most prevalent waterborne pathogens in RWI for children
- 6) Incorporate results of environmental monitoring (e.g. which pathogens were assessed in the water body/sample, method of detection, species detected, prevalence)
- 7) How are illness rates and severity different between the exposed children and adults?
- 8) Create a ranking of the most prevalent RWI and health outcomes across all age groups, where the data permits

The contractor shall summarize and compare illness rates/health outcomes from the outbreak, epidemiologic or other health studies for children versus adults. Published risk assessments (e.g., quantitative microbial risk assessments (QMRA)) shall also be considered. More recent epidemiological analyses have suggested that there is a risk differential for children. Part of this analysis shall evaluate the context for the reported risk differential (e.g., sources of pathogens, exposure differences, study locations, fecal loading profiles, etc.). Outcomes may be expressed as relative risks, odds ratios, fatality rates/deaths, and should include confidence levels. Tables, figures or other appropriate graphical representation should be employed.

EPA is interested in evaluating these various areas in the development and implementation of new recreational AWQC. The contractor, in conjunction with the WACOR, shall develop risk-based analyses based on EPA's previous QMRA efforts and incorporating updated exposure profiles using the information gleaned from the above efforts. For example, the NEEAR epi studies did not report a significant health relationship with FIB for children (as opposed to the general population in the study). Given that children tend to have higher exposures while recreating, ingest more water when recreating (see Dufour study results – will be provided by the WACOR), may be more susceptible to infection (e.g., norovirus), and can have more severe outcomes once infected (e.g., E. coli O157) could the exposure profile (i.e., their behavior in shallow water) for children have an ameliorating impact? NEEAR also did not report significant health relationships in shallow water; precisely where most children are exposed. The contractor shall utilize existing QMRA approaches and epidemiology and/or other health information to evaluate the potential impacts of the exposure profile of children on the expected results for human health risks.

Understanding children's risks and their life stage-specific exposure patterns has been an ongoing effort at EPA. The WACOR will provide the contractor with the background information that has already been collected in this area. The contractor shall use this information as a starting point to develop the project report. The contractor shall conduct literature searches for the years 2011 to the present in the area of children's exposure parameters and health effects children experience following exposure to microbially-contaminated surface waters. References collected, but not used will also require proactive justification. The contractor shall leverage efforts under 2-03 (The development

of cyanotoxin ambient water quality criteria) with this task as the criteria contains an assessment of children's exposure parameters. The contractor shall ensure that no duplication of effort occurs, such as searching the scientific literature or evaluating sensitive subpopulations. The contractor shall prepare and submit a draft report for EPA technical review detailing the information collected and analyzed for the evaluation of human health risks to children from recreational exposure to ambient waters affected by microbial contamination. Teleconference via phone/Skype may be required to discuss the weight of evidence provided by the contractor.

The contractor shall revise the report based on the comments submitted by the WACOR and discuss options for addressing the comments with EPA. The contractor shall also prepare effective communication materials to accompany the draft report for use in internal and eventually external communication efforts (see Task 3).

The report may undergo multiple edits and the contractor is expected to respond to EPA comments. The contractor shall incorporate comments on any draft deliverables, and all documents be formatted as directed by the EPA WACOR through written technical direction. Also, the contractor shall update information in the report as needed to capture any developments related to ongoing studies. The report shall be compliant with Section 508 of the Rehabilitation Act when finalized and submitted (see <http://www.epa.gov/accessibility/index.htm>).

The contractor shall prepare and submit a version of the final report based on the deliverable that would be suitable for external scientific peer review. The contractor shall also submit a draft to the WACOR for Agency clearance. When all Agency comments have been addressed, that version may be submitted for peer review. The venue for the peer review is currently undetermined. The contractor shall address peer reviewer comments in conjunction with the WACOR. This document shall be formatted for publication as directed by the WACOR.

Travel: No contractor's travel outside of the Washington, D.C. metro area is anticipated for this task.

Task Area 3: *Communication materials*

As specified in the Task 2, the contractor shall prepare, in conjunction with the WACOR, materials to assist in communicating the complex technical aspects of the project results to both non-technical and technical (but not academic) audiences (both internal and external to the Agency). These materials will most likely consist of synopses, executive summaries, Q&As, presentation slides, etc. and each may be aimed at a particular audience or tailored for the communication need. The contractor shall coordinate with the WACOR on the scope and nature of these materials for specific audiences.

Task Area 4: General Project Support

The contractor shall, based on technical direction given by the WACOR, provide support in preparing interim project update sand/or other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractor may be requested to participate in and/or conduct briefings and/or present at meetings. It is estimated that this task should not require more than 5 – 10 % of the total LOE allotted to this work assignment.

| Task No. | Milestones/Deliverable* | Schedule |
|-----------------|---|--|
| 1 | 1.1 Workplan | Per contract requirements |
| 1 | 1.3 Information Quality Guidelines | Submitted with final deliverables |
| 2 | Perform literature search to gather the most recent information of children's exposure patterns, susceptibility and risks from microbial contaminants in water. | Within 1 month of workplan approval. |
| 2 | Evaluate existing health information for children's exposure to microbial contaminants in water. Discuss results with WACOR | Within 2 months of workplan approval |
| 2 | Submit draft report for EPA review | Within 2 weeks of discussion of results with WACOR |
| 2 | Respond to EPA reviewer comments | Within 2 weeks of receiving EPA comments |
| 2 | Submit final report to EPA for peer review clearance | Within 2 weeks of addressing comments |
| 2 | Respond to peer reviewer comments | Within 2 weeks of receiving comments |
| 3 | Prepare risk communication presentation materials for technical and non-technical audiences | TBD by technical direction |
| 4 | General project support | On-going |

General Requirements of the Work Assignment and Schedule:

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. WACOR will provide comments on draft submissions prior to submission of final documents.

Final Documents: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Technical Direction:

The WACOR or an authorized individual is permitted to provide technical direction. Technical direction must be within the scope of the statement of work of the contract and includes: (1) Direction to the contractor which assists the contractor in accomplishing the Statement of Work, incurring no additional costs agreed upon in the approved work plan, (2) Comments on and approval of reports or other deliverables. Technical direction will be issued in writing or confirmed in writing within five (5) calendar days after verbal issuance. One copy of the technical direction memorandum will be forwarded to the Contracting Officer, Contract Specialist, and the Contract-Level Contracting Officer Representative.

Contractor Identification:

All contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, the contractor personnel shall wear a badge which identifies the individual as a contractor employee. All contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

Confidentiality:

Some of the work assigned under these tasks will be to draft, edit and review sensitive program and organizational information. The contractor shall not discuss the contents of the conference or meeting discussions with anyone that did not participate in those discussions.

Notice Regarding Guidance Provided under this Work Assignment:

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the EPA COR and the EPA Contracting Officer.

References

CDC Rec Water Outbreaks:

Alphabetical index of Water-Related Health Data:

CDC Healthy Swimming Webpage: <http://www.cdc.gov/healthywater/swimming/data/>

Epidemiological studies:

“High Sensitivity of Children to Swimming-Associated Gastrointestinal Illness Results Using a Rapid Assay of Recreational Water Quality” Timothy J. Wade, Rebecca L. Calderon, Kristen P. Brenner, Elizabeth Sams, Michael Beach, Richard Haugland, Larry Wymer, and Alfred P. Dufour (Epidemiology 2008;19: 375–383)
http://journals.lww.com/epidem/Abstract/2008/05000/High_Sensitivity_of_Children_to.8.aspx

Marine Studies (P1, 2):

“Rapidly measured indicators of recreational water quality and swimming-associated illness at marine beaches: A prospective cohort study” Timothy J Wade, Elizabeth Sams, Kristen P Brenner , Rich Haugland , Eunice Chern , Michael Beach , Larry Wymer, Clifford C Rankin , David Love , Quanlin Li , Rachel Noble and Alfred P Dufour - Environmental Health 2010, 9:66doi:10.1186/1476-069X-9-66
Published: 31 October 2010

- Table S2: Adjusted Odds Ratios for illness risk among swimmers for a 1 log10 Increase in indicator density. Children age 10 and under.

<http://www.ehjournal.net/imedia/3968942414721357/supp2.pdf>

Epidemiological study in marine waters impacted by urban runoff in a temperate region (CD 5(a)):

“Report on 2009 National Epidemiologic and Environmental Assessment of Recreational Water Epidemiology Studies” Timothy J Wade, Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010. USEPA Report Number: EPA/600/R-10/168.

- Table 4.5, 4.6: Water exposures among children
- Tables 4.8-4.12: Incidence of illness among children
- Table 4.39, 4.42, 4.56, 4.57,
- Figure 5.16: Incidence of illness among children with regard to measures of water quality.

<http://water.epa.gov/scitech/swguidance/waterquality/standards/criteria/health/recreation/index.cfm>

Epidemiological study in a tropical region (CD 5(b)):

“Report on 2009 National Epidemiologic and Environmental Assessment of Recreational Water Epidemiology Studies” Timothy J Wade , Elizabeth A Sams,

Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010. USEPA Report Number: EPA/600/R-10/168.

Wade, T. J., R. L. Calderon, et al. (2006). "Rapidly measured indicators of recreational water quality are predictive of swimming-associated gastrointestinal illness." *Environ Health Perspect* 114(1): 24-8.

Wade, T. J., N. Pai, et al. (2003). "Do U.S. Environmental Protection Agency Water Quality Guidelines for Recreational Waters Prevent Gastrointestinal Illness? A Systematic Review and Meta-analysis." *Environmental Health Perspectives* 111(8): 1102-1109.

Colford, J. M., Jr., T. J. Wade, et al. (2007). "Water Quality Indicators and the Risk of Illness at Beaches With Nonpoint Sources of Fecal Contamination." *Epidemiology* 18(1): 27-35.

Fleisher, J. M., F. Jones, et al. (1993). "Water and non-water-related risk factors for gastroenteritis among bathers exposed to sewage-contaminated marine waters." *International Journal of Epidemiology* 22(4): 698-708.

Fleisher, J. M., D. Kay, et al. (1996). "Marine waters contaminated with domestic sewage: nonenteric illnesses associated with bather exposure in the United Kingdom." *Am J Public Health* 86(9): 1228-34.

Kay, D., J. M. Fleisher, et al. (1994). "Predicting likelihood of gastroenteritis from sea bathing: results from randomised exposure." *Lancet* 344(8927): 905-9.

Wiedenmann, A., P. Kruger, et al. (2006). "A randomized controlled trial assessing infectious disease risks from bathing in fresh recreational waters in relation to the concentration of *Escherichia coli*, intestinal enterococci, *Clostridium perfringens*, and somatic coliphages." *Environ Health Perspect* 114(2): 228-36.

Kay, D., N. Ashbolt, et al. (2006). "Reply to comments on "Derivation of numerical values for the World Health Organization guidelines for recreational waters"." *Water Res* 40(9): 1921-5.

Kay, D., J. Bartram, et al. (2004). "Derivation of numerical values for the World Health Organization guidelines for recreational waters." *Water Res* 38(5): 1296-304.

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|---|----------------|--|-------------------------------|---|----------------------------|---|---------------------------------|-------------------------|------------------|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 3-03 | | | |
| | | | | | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | |
| Contract Number EP-C-16-011 | | Contract Period 11/01/2016 To 06/30/2020 Base Option Period Number 3 | | Title of Work Assignment/SF Site Name Cyanotoxin and HAB support | | | | | |
| Contractor ICF Incorporated, L.L.C. | | | | Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6, 3.8 | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 07/01/2019 To 06/30/2020 | | | |
| Comments: | | | | | | | | | |
| <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div> | | | | | | | | | |
| Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | | | |
| SFO <input type="checkbox"/> (Max 2) | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) (Cents) | Site/Project (Max 8) | Cost Org/Code |
| 1 | | | | | | | | | |
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| Authorized Work Assignment Ceiling | | | | | | | | | |
| Contract Period: | | Cost/Fee: | | LOE: | | | | | |
| 11/01/2016 To 06/30/2020 | | | | | | | | | |
| This Action: | | | | | | | | | |
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| Total: | | | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | |
| Contractor WP Dated: | | | | Cost/Fee | | LOE: | | | |
| Cumulative Approved: | | | | Cost/Fee | | LOE: | | | |
| Work Assignment Manager Name John Ravenscroft <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: | | | |
| | | | | | | Phone Number: 202-566-1101 | | | |
| | | | | | | FAX Number: | | | |
| Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: | | | |
| | | | | | | Phone Number: 202-566-1107 | | | |
| | | | | | | FAX Number: | | | |
| Other Agency Official Name Shirley Harrison <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: | | | |
| | | | | | | Phone Number: 202-566-1107 | | | |
| | | | | | | FAX Number: | | | |
| Contracting Official Name Kathleen Rechenberg <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: | | | |
| | | | | | | Phone Number: 513-487-2853 | | | |
| | | | | | | FAX Number: | | | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT # EP-C-16-011
WORK ASSIGNMENT #3-03**

Title: Activities to support the development of human health Ambient Water Quality Criteria (AWQC) for Cyanotoxins

Work Assignment Contracting Officer's Representative (WACOR):

John Ravenscroft (Mail Code 4304T)
U.S. Environmental Protection Agency (US EPA)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

Alternate WACOR:

Lesley D'Anglada (Mail Code 4304T)
Phone (202) 566-1125
E-mail: danglada.lesley@epa.gov

Period of Performance: July 1, 2019 through June 30, 2020

Contract PWS: 3.1, 3.3, 3.6, 3.8

****Note: No Confidential Business Information (CBI) data will be needed in the course of this work assignment.**

Background:

National Ambient Water Quality Criteria (AWQC) are established by the United States Environmental Protection Agency (EPA) pursuant to Section 304(a) of the Clean Water Act (CWA). The main goal of the CWA is to restore and maintain the chemical, physical, and biological integrity of the nation's waters. AWQC are recommendations developed and published by the EPA reflecting the latest scientific knowledge: (A) on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation which may be expected from the presence of pollutants in any body of water, including ground water; (B) on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes; and (C) on the effects of pollutants on biological community diversity, productivity, and stability, including information on the factors affecting rates of eutrophication and rates of organic and inorganic sedimentation for varying types of receiving waters. CWA §304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting pollutant concentrations in ambient water. They are a non-regulatory, scientific assessment of effects on human health or aquatic life. The criteria recommendations developed from this effort are intended to be such scientific assessments.

The Environmental Protection Agency's (EPA) AWQC recommendations may be used by the states to establish water quality standards (WQS), and if adopted in state WQS and approved by EPA, will ultimately provide a basis for protecting the health of those recreating on or in the nation's waters. Additionally, the criteria also provide guidance to EPA when promulgating WQS for states under CWA §303(c), when such actions are necessary. When states adopt new or revised AWQC into WQS, they must be scientifically defensible and protective of the designated uses of the waterbodies. EPA's regulation 40 CFR §131.11(b)(1) provides that "In establishing criteria, states should (1) Establish numerical values based on (i) 304(a) Guidance; or (ii) 304(a) Guidance modified to reflect site-specific conditions; or (iii) Other scientifically defensible methods." For example, EPA published human health recreational water quality criteria (RWQC) recommendations in 2012 to describe the desired ambient water quality conditions to support the designated use of primary contact recreation (EPA, 2012). The 2012 RWQC are designed to protect swimmers from excess gastrointestinal illness caused by pathogens present in fecal contamination of waterbodies. This §304(a) criteria document recommends ambient water quality criteria values for cyanotoxins that would be protective of human health given a primary contact recreational exposure scenario. The cyanotoxins included in this effort have been demonstrated to occur in nutrient-enriched waters affected by a proliferation of cyanobacteria. Any recommended values produced from this effort do not replace or supersede the 2012 RWQC recommendations for recreational waters. Rather they are offered to supplement the 2012 RWQC to provide additional public health protection for additional, potentially hazardous conditions found in ambient recreational waters.

The water quality criteria developed from this effort are national ambient water quality criteria recommendations for the protection of human health. Unless expressly indicated otherwise, all references to "criteria", "water quality criteria", "ambient water quality criteria (AWQC) recommendations," or similar variants thereof, are references to national ambient water quality criteria recommendations for human health.

Quality Assurance:

The tasks (Tasks 2 -6) in this work assignment (WA) require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the approved ICF March 2017 final Programmatic QAPP (pQAPP) to assure the quality of the data used under this work assignment. The scope of the March 2017 pQAPP covers secondary data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved pQAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the QA/quality control (QC) procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

Tasks:

Task Area 1 – Work Plan and Monthly Progress Reports

Task Area 1.1. Work Plan

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task Area 1.2. Monthly Progress Reports

This task includes monthly progress and financial reports. The monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

As described in the Quality Assurance Section, the contractor must comply with the ICF March 2017 approved pQAPP for the use of secondary data and, if applicable, application of peer reviewed existing model. The monthly progress report shall indicate, in a separate QA section, whether significant project-specific QA issues have been identified and how they are being resolved.

Task 1.3: Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines (<https://www.epa.gov/quality/epa-information-quality-guidelines>) and shall complete the Checklist for Influential Information, as needed, for each deliverable from this work assignment. The WACOR will provide this checklist to the contractor. The contractor shall have a teleconference with the WACOR before the initiation of Task 2 to discuss the Information Quality Guidelines and the contractor's role in completing the checklist. At the end of the work assignment, the contractor shall provide a memorandum describing how the planned product(s) developed for this work assignment meet with EPA's Checklist for Influential Information and documenting the quality assurance procedures that were used in developing the deliverables under this PWS.

Task Area 2 - Support for developing and editing cyanotoxin AWQC and AWQC-related documents

Task Area 2.1. AWQC development

The contractor shall assist the WACOR in developing AWQC documents or other related documents for cyanotoxins for the protection of human health. Risks from exposure to cyanobacteria can fall into two main categories: 1) inflammatory health endpoints associated with direct contact with the cells, and 2) intoxications via cyanotoxins produced by the bacteria. Cyanobacteria, also known as 'blue-green algae,' and are classified as microbial pollutants. The contractor shall refer to EPA's *Methodology for Deriving Ambient Water Quality Criteria for the*

Protection of Human Health (2000) for a discussion of EPA's approved framework and parameter selection process. The document in development shall conform to Agency risk assessment guidance and be accessible to a non-technical audience for the purposes of informing decision-making. This task is iterative in nature and may require multiple revisions prior to publishing a final AWQC document. Analyses of monitoring data, such as characterizing correlations between toxin levels in surface waters and cyanobacterial cell counts or total phosphorus concentrations, may be necessary to support decisions in the development of the AWQC. White papers discussing specific topics and targeted literature searches may be needed (e.g., identification, collation and discussion of the amount of toxin produced by a cyanobacterial cell).

The contractor shall perform technical and editorial edits for all documents prepared and submit to the WACOR. Items, such as active voice and clear writing style, shall be addressed prior to submitting milestone deliverables (e.g., draft) to EPA. The contractor shall meet with the WACOR to discuss project planning and scoping prior to beginning work and then periodically thereafter, as needed. EPA recently published the recommendations for microcystin and cylindrospermopsin; additional toxins may be added to those recommendations in the future.

Task Area 2.2. Prepare briefing materials and other supporting documents to aid in AWQC development and communication efforts

Briefing materials and other supporting documents will be needed during Final Agency Review, and during other parts of the Criteria development process. The contractor shall aid in the development of any materials or presentations for these purposes. It is anticipated that major decision points and/or document development milestones will require management briefings and supporting materials.

Task Area 3 – Response to Comments

Task Area 3.1. Organizing and responding to comments.

Draft AWQC will undergo several types of reviews before a final version is posted, including: internal management and technical reviews, expert peer-reviews, and public comment period. The contractor shall assist the WACOR with the response to comments for all reviews, revise the AWQC documents as requested, and provide an updated version to the WACOR. For the draft document, the contractor can anticipate internal and external technical peer review comments and internal EPA office review comments. Additionally, the contractor should anticipate 3 rounds of management review at various levels.

Task Area 3.2. Public Comment Analysis for the AWQC.

The contractor shall continue to support EPA with addressing public comments on the published draft AWQC. Efforts under this task may also include comment analysis and summaries.

Task Area 4 – Gathering and preparing materials for the EPA docket

A “docket” is a collection of documents made available by an agency for public viewing often associated with an opportunity for public comment. EPA's dockets consist of materials used in developing a particular rulemaking or other action issued by the Agency. This task supported the

publication of the draft criteria document in the Federal Register during the base year. EPA does not anticipate significant efforts under this task during option year 3. The task remains in this work assignment in case EPA would need to provide additional docket materials.

Task Area 4.1. Prepare comprehensive list of materials needed in the docket

The contractor shall help identify materials that need to be placed in the EPA docket. Docket materials may include, but are not limited to, publications, data, and meeting notes.

Task Area 4.2. Gather and prepare materials needed in the docket

Once the docket materials list has been reviewed by the WACOR, the contractor shall help gather and prepare all the materials that need to be placed in the EPA docket. Again, docket materials may include, but are not limited to, publications, data, and meeting notes.

Task Area 5 – Support Action Development Process Workgroup (ADP WG) efforts in the development of the RWQC

This task will require the contractor to assist in efforts of the ADP WG. The contractor shall attend on-site ADP WG meetings, provide note-taking support, and submit meeting notes to the WACOR within 2 business days of each ADP WG meeting. Additionally, the contractor shall prepare meeting materials that may include, but are not limited to, presentations, briefing materials, hand-outs, and overviews. The number of workgroup meetings will depend on the number of decisions that require inter-office input, which is not known at this time. However, not more than 6 meetings are anticipated. The types of materials needed for each meeting will vary depending on the workgroup's need and topics discussed. Since EPA published cyanotoxin recommendations in May 2019, EPA does not anticipate additional effort under this task in the near future. However, the task is maintained here in case the Agency adds additional toxins to the existing recommendations, which would require an internal workgroup process to develop.

Travel: Local travel is anticipated for this Task. No contractor travel outside of the Washington, D.C. metro area is required.

Task Area 6 - General Project Support

The contractor shall, based on written technical direction given by the WACOR, provide support in conducting literature searches of the peer reviewed scientific literature—to address identified data gaps the searches would be specific and targeted in nature—and in preparing interim project updates and other materials for internal and external audiences. Literature searches will aid the development of documents prepared under Task 2. It is not known at this time how many searches would be needed, but for planning purposes, the contractor may plan on four targeted searches. Additionally, specific data analyses may be required for briefings and/or communication materials. Such analyses would be based on written technical direction provided by the WACOR. These analyses are generally to support decision-making and usually have a defined scope to address specific risk management questions. Updates and other support materials may include, but are not limited to, short briefing documents, white papers and PowerPoint presentations. The WACOR may request the contractor to participate in and/or conduct briefings. A weekly update call with the WACOR may be required for this work assignment, on an as needed basis.

Some meetings may require contractor support and/or attendance for note-taking, presentations, meeting preparation materials, and other logistical support. Details on meeting dates and locations will be provided by the WACOR through written technical direction, as further information becomes available. For planning purposes, the contractor can anticipate 3 meetings.

Travel: Contractor is located within the Washington D.C. commuting area. Contractor travel outside of the Washington, D.C. metro area for 1 person may need to occur for this work assignment. Travel shall be in accordance with the requirements of the contract.

General Requirements of the Work Assignment and Schedule:

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be provided through written technical direction from the EPA WACOR.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.

Final Documents: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Milestone/Deliverable Table.

| Task | Task # | Milestones and Due Dates |
|--|--------|---|
| Task 1: Work plan, monthly progress reports and quality assurance | | |
| Workplan | 1.1 | Per contract requirements |
| Information Quality Guidelines | 1.2 | Discuss with WACOR within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials). |
| Task 2: Support for developing and editing cyanotoxin AWQC and AWQC-related documents | | |
| AWQC development | 2.1 | After the workplan approval, throughout the period of performance. Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed. |
| Prepare briefing materials and other supporting documents to aid in AWQC development and communication efforts | 2.2 | To Be Determined (TBD) by internal management needs in support of developing AWQC. |
| Task 3: Response to Comments | | |
| Organizing and responding to comments | 3.1 | Activity under this task not expected in the near term. Task is maintained in case comments are sought for additional toxins. Exact dates TBD. |
| Public Comment Analysis for the AWQC | 3.2 | Activity under this task not expected in the near term. Task is maintained in case comments are sought for additional toxins. Exact dates TBD. |
| Task 4: Gathering and preparing materials for the EPA docket | | |
| Prepare comprehensive list of materials needed in the docket | 4.1 | Activity under this task not expected in the near term. Task is maintained in case comments are sought for additional toxins. Exact dates TBD. |
| Gather and prepare materials needed in the docket | 4.2 | Activity under this task not expected in the near term. Task is maintained in case comments are sought for additional toxins. Exact dates TBD. |
| Task 5: Support for ADP WG | | Activity under this task not expected in the near term. Task is maintained in case comments are sought for additional toxins. Exact dates TBD. |
| Task 6: General Project Support | | On-going |

MEETINGS, CONFERENCES, TRAINING EVENTS, AWARD CEREMONIES AND RECEPTION:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA Contract Level Contracting Officer's Representative (CL-COR) as needed and provided to the Contracting Officer (CO). Work under conference related activities that involves \$20,000 or more in net expenses shall not occur until this approval is obtained and provided by the CO.

TECHNICAL DIRECTION:

The WACOR or the Alternate WACOR is permitted to provide technical direction. Technical direction must be within the statement of work of the contract and includes: (1) Direction to the contractor which assists the contractor in accomplishing the Statement of Work, (2) Comments on and approval of reports or other deliverables. Technical direction will be issued in writing or confirmed in writing within five (5) calendar days after verbal issuance. One copy of the technical direction memorandum will be forwarded to the CO and the CL-COR.

CONTRACTOR IDENTIFICATION:

The contractor personnel shall clearly identify corporate affiliation at the start of any meeting. While attending EPA-sponsored meetings, conferences, symposia, etc. or while on a Government site, contractor personnel shall wear a badge which identifies the individual as a contractor employee. The contractor personnel are strictly prohibited from acting as a representative of the Agency at meetings, conferences, symposia, etc.

SPECIAL CONDITIONS:

- A. The contractor shall provide all materials written under these tasks to the WACOR, as per work assignment, in electronic form and 5 hard copies of the final products. Electronic versions shall be in Microsoft Word and/or PDF.
- B. The contractor shall provide signed copies of all consultant agreements for the experts required in support of this work assignment to the EPA Contracting Officer.

CONFIDENTIALITY:

Some of the work assigned under these tasks will be to draft, edit and review sensitive program and organizational information. The contractor shall not discuss the contents of the conference or meeting discussions with anyone that did not participate in those discussions.

NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT:

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherently governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the WACOR or the EPA Contracting Officer.

| | | | | | | | | | | |
|---|---|--|-------------------------------|----------------------------|----------------------------|-------------------------|----------------------------|---------|-------------------------|------------------|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | Work Assignment Number 3-03 | | | | | | | | |
| | | <input type="checkbox"/> Other <input checked="" type="checkbox"/> Amendment Number: 000001 | | | | | | | | |
| Contract Number EP-C-16-011 | Contract Period 11/01/2016 To 06/30/2020 Base Option Period Number 3 | Title of Work Assignment/SF Site Name Cyanotoxins and HABS | | | | | | | | |
| Contractor ICF Incorporated, L.L.C. | | Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6, 3.8 | | | | | | | | |
| Purpose: <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input checked="" type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | Period of Performance From 07/01/2019 To 01/23/2020 | | | | | | | | |
| Comments: The subject WA is hereby cancelled in its entirety, the work is no longer required. Therefore, all work under this contract shall stop work effective 1/23/2020. | | | | | | | | | | |
| <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund | | | | | | | | | | |
| SFO <input type="checkbox"/> (Max 2) Note: To report additional accounting and appropriations date use EPA Form 1900-69A. | | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) | (Cents) | Site/Project (Max 8) | Cost Org/Code |
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| Authorized Work Assignment Ceiling | | | | | | | | | | |
| Contract Period: | | Cost/Fee: | | LOE: | | | | | | |
| 11/01/2016 To 06/30/2020 | | | | | | | | | | |
| This Action: | | | | | | | | | | |
| Total: | | | | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | | |
| Contractor WP Dated: | | | | Cost/Fee | | | | LOE: | | |
| Cumulative Approved: | | | | Cost/Fee | | | | LOE: | | |
| Work Assignment Manager Name John Ravenscroft | | | | | | | Branch/Mail Code: | | | |
| _____ (Signature) (Date) | | | | | | | Phone Number: 202-566-1101 | | | |
| | | | | | | | FAX Number: | | | |
| Project Officer Name Shirley Harrison | | | | | | | Branch/Mail Code: | | | |
| _____ (Signature) (Date) | | | | | | | Phone Number: 202-566-1107 | | | |
| | | | | | | | FAX Number: | | | |
| Other Agency Official Name | | | | | | | Branch/Mail Code: | | | |
| _____ (Signature) (Date) | | | | | | | Phone Number: | | | |
| | | | | | | | FAX Number: | | | |
| Contracting Official Name Donna Reinhart | | | | | | | Branch/Mail Code: | | | |
| _____ (Signature) (Date) | | | | | | | Phone Number: 513-487-2114 | | | |
| | | | | | | | FAX Number: | | | |

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|---|----------------|--|-------------------------------|--|----------------------------|---|---------------------------------|-------------------------|------------------|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 3-04 | | | |
| | | | | | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | |
| Contract Number EP-C-16-011 | | Contract Period 11/01/2016 To 06/30/2020 Base Option Period Number 3 | | Title of Work Assignment/SF Site Name Coliphage RWQC development | | | | | |
| Contractor ICF Incorporated, L.L.C. | | | | Specify Section and paragraph of Contract SOW 3.1, 3.2, 3.3, 3.4, 3.6, 3.7, 3.8 | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 07/01/2019 To 06/30/2020 | | | |
| Comments: Immediate Start Authorized | | | | | | | | | |
| <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div> | | | | | | | | | |
| Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | | | |
| SFO <input type="checkbox"/> (Max 2) | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) (Cents) | Site/Project (Max 8) | Cost Org/Code |
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| Authorized Work Assignment Ceiling | | | | | | | | | |
| Contract Period: | | Cost/Fee: | | LOE: | | | | | |
| 11/01/2016 To 06/30/2020 | | | | | | | | | |
| This Action: | | | | | | | | | |
| Total: | | | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | |
| Contractor WP Dated: | | | | Cost/Fee | | LOE: | | | |
| Cumulative Approved: | | | | Cost/Fee | | LOE: | | | |
| Work Assignment Manager Name Sharon Nappier | | | | | | Branch/Mail Code: | | | |
| <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div> | | | | | | Phone Number: 202-566-0740 | | | |
| | | | | | | FAX Number: | | | |
| Project Officer Name Shirley Harrison | | | | | | Branch/Mail Code: | | | |
| <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div> | | | | | | Phone Number: 202-566-1107 | | | |
| | | | | | | FAX Number: | | | |
| Other Agency Official Name Shirley Harrison | | | | | | Branch/Mail Code: | | | |
| <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div> | | | | | | Phone Number: 202-566-1107 | | | |
| | | | | | | FAX Number: | | | |
| Contracting Official Name Kathleen Rechenberg | | | | | | Branch/Mail Code: | | | |
| <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between;"> <div>(Signature)</div> <div>(Date)</div> </div> | | | | | | Phone Number: 513-487-2853 | | | |
| | | | | | | FAX Number: | | | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-16-011
WORK ASSIGNMENT #3-04**

Title: Activities to support the development of Recreational Water Quality Criteria (RWQC) for Coliphage and additional priorities outlined in the 2017 Review of the 2012 RWQC

Work Assignment Contracting Officer Representative (WACOR):

Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

Alternate WACOR:

Lesley D'Anglada (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1125
E-mail: danglada.lesley@epa.gov

Period of Performance: July 1, 2019 through June 30, 2020

Contractor SOW: 3.1, 3.2, 3.3, 3.4, 3.6, 3.7, 3.8

****Note: No CBI data will be needed in the course of this work assignment.**

BACKGROUND:

Human health recreational water quality criteria (RWQC) are numeric values limiting the amount of chemical or microbial agents present in our nation's waters. Human health criteria are developed under Section 304(a) of the Clean Water Act (CWA) of 1972 and are designed to protect human health. Water quality criteria are developed by assessing the relationship between pollutants and their effect on human health and the environment. These criteria are used by states and Indian tribes to establish water quality standards and ultimately provide a basis for controlling discharges or releases of pollutants.

The Environmental Protection Agency (EPA) has published RWQC for bacteria. Historically EPA has based the bacteria criteria on fecal indicator bacteria (FIB). These organisms do not generally cause human illness themselves (that is, they are not human pathogens); rather, they are indicators of fecal contamination and therefore indicators of the potential presence of human pathogenic organisms.

The EPA is now interested in creating RQWC to protect against viral illnesses using coliphage, a viral indicator. EPA believes that these virus criteria must be scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection.

The EPA recently completed a five-year review of its 2012 Recreational Water Quality Criteria (RWQC) as required by BEACH Act amendments to the Clean Water Act (CWA) Section 304(a)(9)(B). An important goal of this review and report was to document the assessment of whether revisions to the 2012 RWQC are necessary. In this review, the EPA also identified the priorities for further work to utilize this new information so that improvements to public health protection in recreational waters continue. This work assignment will address some of these priorities.

For example, the Review noted there is an increasing body of literature available on the environmental occurrence of Antimicrobial Resistant Bacteria/Antimicrobial Resistant Genes (AMRB/ARGs) in recreational waters. However, to develop a more complete picture, additional research is needed on the incidence, associated risks, and transfer mechanisms in recreational waters, as well on the removal of AMRB/ARGs by wastewater treatment processes. The EPA is in the early stages of developing a broader surveillance strategy and looking for meaningful opportunities to improve human health related to exposures to AMRB/ARGs.

QUALITY ASSURANCE:

Tasks 2 and 3 in this work assignment require the use of existing data and application of existing, peer reviewed models. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the Agency approved ICF March 2017 Programmatic Quality Assurance Project Plan (pQAPP) for Collection, Use, and Analysis (including Model Application) of Existing Data in order to assure the quality of the data used under this work assignment. The scope of the March 2017 pQAPP covers existing data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The contractor shall comply with the March 2007 EPA approved pQAPP. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved pQAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a work assignment-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the Quality Assurance and Quality Control (QA/QC) procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

TASKS:

Task 1: Work Plan and Monthly Progress Reports

Task 1.1 Work Plan

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WACOR via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task 1.2 Monthly Progress Reports

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports shall include a table with the invoice LOE and costs' broken out by the tasks in this WA. These reports shall also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.3 Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines (IQG) (www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information). The contractor shall complete the OW IQG Checklist as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the OW IQG checklist. The WACOR will provide the checklist to the contractor. At the end of the work assignment, the contractor shall provide a memorandum describing how the planned product(s) developed meet the requirements of the OW's IQG checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this work assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report.

TASK 2 – Viral distributions

Task Area 2.1 Literature reviews.

This task is a continuation of earlier efforts to characterize the densities of viruses in raw sewage (influent), in effluent, and in ambient waters. Through written technical direction by the WACOR, the contractor shall collect and evaluate viral density data in the

aforementioned matrices from the peer-review literature, grey literature, and from utilities, when available. Viruses reviews may include, but are not limited to, male-specific and somatic coliphage, norovirus, adenovirus, enterovirus, and reovirus.

Task Area 2.2 Literature review publications.

A series of publications may result from the literature reviews in Task Area 2.1. The contractor shall prepare the data and information for submission, perform edits after the work has received internal EPA reviews, and submit the manuscript to the journal. The contractor shall also be responsible for responding to reviewer comments and completing final edits.

TASK 3 – Recreational Water Quality Criteria Coliphages

Task Area 3.1 Scope of the Criteria Documents

The contractor shall assist in scoping the RWQC for coliphage for potentially multiple designated uses, such as primary contact recreation and drinking water. The contractor shall also assist in drafting an outline of the coliphage-based criterion and identifying the needs of the criterion documents.

Task Area 3.2 Derivation of the Criteria Values

This task is a continuation of earlier efforts to use risk assessment, epidemiology, and other statistical methods to develop RWQC values for coliphage. Risk assessments will rely heavily on data collected in Task 2 through written technical direction by the WACOR. The contractor shall develop RWQC values to be used in future criteria for coliphage.

Task Area 3.3 Develop Criterion Document Drafts

The contractor shall provide draft documents of the RWQC for coliphage as an ongoing effort during the period of performance. A series of Drafts are expected for internal purposes, for peer-review, and for public comment.

Task Area 3.4 Prepare and submit Final RWQC Criteria for Coliphage

The contractor shall prepare and submit a Final RWQC document. This document shall be 508 Compliant and formatted as directed by the WACOR through written technical direction.

Task Area 3.5 Prepare briefing materials and other supporting documents pertaining to the Coliphage-based RWQC documents

The contractor shall aid in the development of any briefing materials, other supporting documents, or presentations needed during the criteria development process.

TASK 4 – Support of Work Identified in the 2017 Five-Year Review of the Recreational Water Quality Criteria

Task Area 4.1 Antimicrobial Resistance(AMR): Literature reviews.

Through written technical direction by the WACOR, the contractor shall collect and evaluate literature related to AMR exposures in the ambient environment from the peer-review literature, grey literature, and from utilities, when available.

Task Area 4.2 Literature review publications.

A series of publications may result from the literature reviews in Task Area 4.2. The contractor shall prepare the data and information for submission, perform edits after the work has received internal EPA reviews, and submit the manuscript to the journal. The contractor shall also be responsible for responding to reviewer comments and completing final edits.

TASK 5- General Project Support

The contractor shall provide support in preparing interim project updates and other materials for internal and external audiences, which will be clarified through written technical direction from the WACOR. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractor shall participate in and/or conduct briefings as needed. A weekly update call with the WACOR will be required for this work assignment.

Some meetings may require contractor support and/or attendance for note-taking, presentations, and meeting preparation materials. Details on travel dates and locations will be provided by the WACOR through technical direction, as further information becomes available.

Travel: Travel may be needed as deemed necessary by the WACOR. This PWS will provide travel funds for up to three trips for contractors and/or subcontractors to travel to Washington DC and to conferences outside of the DC area.

Schedule and Deliverables:

| Task No. | Deliverable | Schedule |
|----------|---|---|
| 1.1 | Workplan | Per contract requirements |
| 2.1 | Literature Reviews | Due within 2 weeks of kick-off call |
| 2.2 | Literature Review publications | Edits to drafts within 3-days of receiving edits from WACOR |
| 3.1 | Scope and outline of RWQC | Due within 2 weeks of kick-off call |
| 3.2 | Criteria derivation efforts | Ongoing |
| 3.3 | RWQC document – DRAFTS (internal, peer-review, public comment) | Edits to drafts within 3-days of receiving edits from WACOR |

| | | |
|-----|---|---|
| 3.4 | RWQC document – FINAL (508) | TBD |
| 3.5 | Briefing materials, supporting documents, presentations | as needed |
| 4.1 | Antimicrobial Resistance: Literature reviews | TBD |
| 4.2 | Literature Review publications | Edits to drafts within 3-days of receiving edits from WACOR |
| 5 | General Project Support | as needed |

Knowledge and Skills Required:

The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology and/or environmental engineering. The contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

General Requirements of the Work Assignment and Schedule:

The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date. The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be issued through written technical direction from the WACOR.

The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. WACOR will provide comments on draft submissions prior to submission of final documents. The contractor shall submit final documents both electronically and in hardcopy to WACOR.

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|---|----------------|----------------------|---|----------------------------|---|---|-----------------------------|-------------------------|------------------|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 3-05 | | | |
| | | | | | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | |
| Contract Number EP-C-16-011 | | | Contract Period 11/01/2016 To 06/30/2020 Base Option Period Number 3 | | | Title of Work Assignment/SF Site Name Activities support water reuse | | | |
| Contractor ICF Incorporated, L.L.C. | | | | | Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.4, 3.6, 3.7, 3.8 | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 07/01/2019 To 06/30/2020 | | | |
| Comments: Immediate Start Authorized | | | | | | | | | |
| <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div> | | | | | | | | | |
| Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | | | |
| SFO <input type="checkbox"/> (Max 2) | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) (Cents) | Site/Project (Max 8) | Cost Org/Code |
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| Authorized Work Assignment Ceiling | | | | | | | | | |
| Contract Period: | | Cost/Fee: | | | LOE: | | | | |
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| This Action: | | | | | | | | | |
| Total: | | | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | |
| Contractor WP Dated: | | | | Cost/Fee | | | LOE: | | |
| Cumulative Approved: | | | | Cost/Fee | | | LOE: | | |
| Work Assignment Manager Name Sharon Nappier | | | | | | | Branch/Mail Code: | | |
| <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> (Signature) (Date) | | | | | | | Phone Number: 202-566-0740 | | |
| | | | | | | | FAX Number: | | |
| Project Officer Name Shirley Harrison | | | | | | | Branch/Mail Code: | | |
| <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> (Signature) (Date) | | | | | | | Phone Number: 202-566-1107 | | |
| | | | | | | | FAX Number: | | |
| Other Agency Official Name Shirley Harrison | | | | | | | Branch/Mail Code: | | |
| <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> (Signature) (Date) | | | | | | | Phone Number: 202-566-1107 | | |
| | | | | | | | FAX Number: | | |
| Contracting Official Name Kathleen Rechenberg | | | | | | | Branch/Mail Code: | | |
| <div style="display: flex; justify-content: space-between;"> <div>_____</div> <div>_____</div> </div> (Signature) (Date) | | | | | | | Phone Number: 513-487-2853 | | |
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**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-16-011
WORK ASSIGNMENT #3-05**

Title: Activities to support the Environmental Protection Agency's (EPA) Water Reuse Efforts

Work Assignment Contracting Officer's Representative (WACOR):

Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

Alternate WACOR:

Lesley D'Anglada (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1125
E-mail: danglada.lesley@epa.gov

Period of Performance: July 1, 2019 through June 30, 2020

Contractor PWS: 3.1, 3.3, 3.4, 3.6, 3.7, 3.8

****Note: No Confidential Business Information data will be needed in the course of this work assignment.**

BACKGROUND:

Currently, there are no Federal regulations for water reuse. Rather, water reclamation and reuse standards in the United States are the responsibility of state and local agencies. In 1980, the Environmental Protection Agency (EPA) developed the first Guidelines for Water Reuse as a technical research report for Office of Research and Development (ORD). There have been several updates to this Guidance, with the most recent being the 2012 Guidelines for Water Reuse.

Indirect Potable Reuse (IPR) occurs when a utility discharges reclaimed water (treated effluent) to an environmental buffer such as a surface water or groundwater supply and this reclaimed water augments the drinking water supply.

Direct Potable Reuse (DPR), for the purposes of this PWS, means the use of water from a regulated wastewater treatment or recycling facility that is introduced into the drinking

water treatment facility without the use of an environmental buffer. For the purposes of this PWS, DPR does not include the introduction of water from a recycling facility directly into a drinking water distribution system.

Non-potable Reuse (NPR) is the use of reclaimed water for recreational, agricultural or other uses where direct human ingestion of the water does not occur. Recreational non-potable reuse can include snowmaking. Agricultural non-potable water reuse includes irrigation of food crops intended for human or animal consumption.

Water availability and drought are driving many states to examine water reuse as an alternative source of water for potable and non-potable applications. In many states, drinking water utilities are at various stages in considering implementing water reuse. An increasing number of states have been contacting EPA asking for guidance when they are approached by utilities that are contemplating or commencing the process of implementing DPR. As of the writing of this PWS, a few states have adopted regulations, guidelines or design standards to cover their water reuse activities. Several states address direct or indirect potable reuse including California, Arizona, New Mexico, Texas, Colorado, Florida, Georgia, Virginia, Wyoming and Washington.

However, there are still scientific gaps relating to potable and non-potable water reuse safety, especially because states are moving forward with different standards and treatment trains and because there is a gap in the knowledgebase for assessing potential human health risks from various routes of exposure to recycled water. For example, many of these safety concerns relate to the risks associated with exposure to chemicals (including mixtures) and microbes in the finished potable water. This work assignment will address human health risks via Quantitative Microbial Risk Assessment (QMRA) from pathogen exposures to various potable and non-potable reuse applications and subsequent exposure routes, including treatment trains currently in use or currently under consideration.

Additionally, the EPA has embarked on an effort to facilitate the development of a Water Reuse Action Plan. The plan covers both potable and non-potable reuse (agriculture/irrigation, industrial, produced water, environmental restoration, and on-site/decentralized reuse) and will better integrate Federal policy and leverage the expertise of both industry and government to ensure the effective use of the Nation's water resources. The National Water Reuse Action Plan will seek to foster water reuse as an important component of integrated water resources management. This work assignment will also address needs for the development and implementation of the Action Plan.

QUALITY ASSURANCE:

The tasks 2 and 3 in this work assignment require the use of existing data and application of existing, peer reviewed models. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the Agency approved ICF March 2017 Programmatic Quality Assurance Project Plan (pQAPP) for Collection, Use, and Analysis (including Model Application) of Existing Data in order to assure the quality of the data

used under this work assignment. The scope of the March 2017 pQAPP covers existing data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The contractor shall comply with the March 2007 EPA approved pQAPP. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved pQAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a work assignment-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the Quality Assurance and Quality Control (QA/QC) procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

Tasks

Task 1: Work plan and Monthly Progress Reports

Task 1.1 Work Plan

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WACOR via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2 Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines (www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information), and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the contractor. The

contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this work assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

Task 2 – Quantitative Microbial Risk Assessment of Water Reuse Scenarios

The contractor shall develop QMRAs to support Health and Ecological Criteria Division (HECD) efforts to estimate human health risks from various exposure routes and water reuse scenarios. The scenarios may include, but are not limited to, defacto, indirect, or direct reuse applications. Non-potable scenarios may also be considered such as, onsite, irrigation, rainwater harvesting). The contractor shall develop appropriate planning and scoping activities prior to conducting risk analyses. Planning and scoping activities will include the delineation of the important risk management questions and potential science gaps that the assessment could address. Additionally, these activities shall include the identification of the exposure routes of interest, relevant pathogens and pathogen indicators, etc. The contractor shall also develop a problem formulation, including a data inventory, for any reuse scenario that is modeled. The contractor shall develop a risk characterization for each QMRA conducted under this task that discusses the interpretation of the risk modeling and analyses. This interpretation shall be a synthesis exercise and include sensitivity and uncertainty analysis and interpretation. The contractor shall frame the risk characterization to reflect the problem formulation such that it is useful for informing decision-making at the EPA. The contractor shall coordinate these activities with the WACOR.

Task 2.1 *Distributions of Pathogens and pathogen indicators*

As part of ongoing work in WA 1-04, the contractor shall update, as specified by the WACOR through written technical direction, distributions of pathogenic protozoa, bacteria, and viruses in raw sewage, ambient water, and in effluent that has undergone various stages of treatment or retention time. Viruses can include coliphage, norovirus, adenovirus, rotavirus, etc. Protozoans can include, but are not limited to, *Giardia spp.* and *Cryptosporidium spp.* Bacteria can include, but are not limited to, *Legionella spp.*, *E. coli* O157:H7, *Campylobacter spp.*, etc. Additionally, the contractor may also be required to develop distributions of pathogen indicators as needed and specified by the WACOR through written technical direction.

Task 2.2 *QMRAs to evaluate water reuse*

Using the pathogen distribution information developed under task 2.1 and/or information provided by the WACOR, the contractor shall conduct QMRAs for estimating human health risks from exposure to waters that have undergone multiple treatment trains and are intended for use under various water reuse scenarios. Multiple treatment train and disinfectant configurations may be explored.

Additionally, as requested by the WACOR, the contractor shall conduct a QMRA for other exposure and water reuse scenarios as needed to help inform decision making in EPA's Office of Water. Risk assessments may include, but are not limited to, defacto reuse, indirect water reuse, and decentralized water reuse configurations. Several circumstances may be evaluated, such as treatment failures and outbreak scenarios.

Task 2.3 *EPA Reports, Technical Guides, and Publications*

The contractor shall submit deliverables from 2.1-2.3 work as both an EPA report for internal review and as a peer-review publication manuscript. EPA anticipates there will be several internal reviews of both the EPA report and manuscript prior to publication. Regarding manuscripts, the contractor shall prepare the data and information for submission, perform edits after the work has received internal EPA reviews, and submit the manuscript to the journal. The contractor shall also be responsible for responding to reviewer comments and completing final edits. At the WACOR's request, the contractor shall make the final EPA reports 508 compliant.

EPA may also choose to publish a series of Technical Guides based on the results conducted in Task 2.1-2.2 and on additional published water reuse literature. The contractor shall assist in outlining, drafting, editing, and finalizing Technical Guides, and the final EPA document shall be 508 compliant.

Travel: Local travel is anticipated for this Task. No contractor travel outside of the Washington, D.C. metro area is required.

Task Area 3 – Water Reuse Action Plan

Task 3.1 *Literature Review*

The contractor shall conduct a literature review specified by the WACOR through written technical direction. Action ideas from the literature will be provided to the WACOR in both spreadsheet and word document formats.

Task 3.2 *Water Reuse Action Plan Development and Action Implementation*

The contractor shall, based on written technical direction given by the WACOR, provide support in the developing the Water Reuse Action Plan. This may include, but is not limited to, synthesizing literature, outreach, and additional information provided by the WACOR. The WACOR anticipates there will be several internal reviews of both the Water Reuse Action Plan prior to publication. The contractor shall also be responsible for responding to reviewer comments and completing final edits. At the WACOR's request, the contractor shall make the final EPA reports 508 compliant

The contractor shall, based on written technical direction given by the WACOR, provide support in the implementing actions of the Water Reuse Action Plan. This may include, but is not limited to, conducting QMRAs, synthesizing literature, and publishing white papers or peer-review manuscripts.

Task Area 4 - General Project Support

The contractor shall, based on written technical direction given by the WACOR, provide support in conducting literature searches of the peer reviewed scientific literature and in preparing interim project updates and other materials for internal and external audiences. Literature searches will aid the development of the QMRAs conducted under Task 2. Updates and other support materials may include, but are not limited to, short briefing documents, white papers and PowerPoint presentations. The contractors may also be requested to participate in and/or conduct briefings. A weekly update call with the WACOR will be required for this work assignment, unless otherwise notified by the WACOR or the contractor.

Some meetings may require contractor support and/or attendance for note-taking, presentations, and/or meeting preparation materials. Details on travel dates and locations, for up to four trips, will be provided by the WACOR through technical direction, as further information becomes available.

Travel: Travel may be needed as deemed necessary by the WACOR to cities such as, but not limited to, Washington DC, San Diego CA, Chicago IL, and/or Chapel Hill, NC.

Knowledge and Skills Required: The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology. The contractor shall be familiar with viral, protozoan, and bacterial indicators and pathogens, microbiological analytical methods (including molecular techniques), biostatistics, quantitative microbial risk assessment, environmental engineering, and direct and indirect potable water reuse. The contractor shall be familiar with the interpretation of indicator and pathogen monitoring results and how those results are related to risk estimates and public health protection.

General Requirements of the Work Assignment and Schedule:

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be issued through written technical direction by the WACOR.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.

Final Documents: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Milestone/Deliverable Table

| Task | Task # | Milestones and Due Dates |
|--|--------|--|
| Task 1: Work plan, monthly progress reports and quality assurance | | |
| Workplan | 1.1 | Per contract requirements |
| Information Quality Guidelines | 1.2 | Discuss with WACOR within 20 calendar days after receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials). |
| Task 2: Quantitative Microbial Risk Assessment | | Ongoing. For each QMRA that is conducted, the contractor shall meet with the WACOR to discuss planning and scoping and develop the problem formulation. |
| Updated distributions of pathogens and pathogen indicators | 2.1 | To Be Determined (TBD) |
| QMRAs | 2.2 | TBD |
| PA Reports, Technical Guides, and Peer-reviewed Publications | 2.3 | <p>Unless specified by the WACOR, the schedule for report and manuscript deliverables is as follows (please note that not all draft deliverable milestones will apply to all deliverables):</p> <p>Reports/Technical Guides: Draft for Mgmt review – 2 weeks after receiving WACOR comments; Draft for peer review – 1 week after receiving EPA Mgmt. comments; Final for Mgmt review – 2 weeks after receiving peer review comments; Final for publication – 2 weeks after receiving EPA Mgmt comments.</p> <p>Manuscripts: Draft for Mgmt review – 2 weeks after receiving WACOR comments; Final – 1 week after receiving EPA Mgmt comments and approval.</p> |
| Task 3: Water Reuse Action Plan | | Initial planning meeting to be held within 20 calendar days after receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed. |
| 3.1 Literature Review | | On-going |
| 3.2 Water Reuse Action Plan Development and Implementation | | TBD |
| Task 4: General Project Support | | On-going |

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| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 3-06 | | | |
| | | | | | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | |
| Contract Number EP-C-16-011 | | Contract Period 11/01/2016 To 06/30/2020 Base Option Period Number 3 | | Title of Work Assignment/SF Site Name Analyses Review of 2012 RWQC | | | | | |
| Contractor ICF Incorporated, L.L.C. | | | | Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.4, 3.6, 3.8 | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 08/29/2019 To 06/30/2020 | | | |
| Comments: *Immediate Start Authorized | | | | | | | | | |
| <div style="display: flex; justify-content: space-between;"> <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund </div> | | | | | | | | | |
| Note: To report additional accounting and appropriations data use EPA Form 1900-69A. | | | | | | | | | |
| SFO <input type="checkbox"/> (Max 2) | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) (Cents) | Site/Project (Max 8) | Cost Org/Code |
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| Work Plan / Cost Estimate Approvals | | | | | | | | | |
| Contractor WP Dated: | | | | Cost/Fee | | LOE: | | | |
| Cumulative Approved: | | | | Cost/Fee | | LOE: | | | |
| Work Assignment Manager Name Sharon Nappier | | | | | | Branch/Mail Code: | | | |
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| | | | | | | FAX Number: | | | |
| Project Officer Name Shirley Harrison | | | | | | Branch/Mail Code: | | | |
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| | | | | | | FAX Number: | | | |
| Other Agency Official Name Shirley Harrison | | | | | | Branch/Mail Code: | | | |
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| | | | | | | FAX Number: | | | |
| Contracting Official Name Angela Lower | | | | | | Branch/Mail Code: | | | |
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| | | | | | | FAX Number: | | | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-16-011
WORK ASSIGNMENT #3-06**

TITLE: Analyses Associated with 2017 Review of the 2012 Recreational Water Quality Criteria

**WORK ASSIGNMENT CONTRACTING OFFICER REPRESENTATIVE
(WACOR):**

Sharon Nappier (Mail Code 4304T)
Health and Ecological Criteria Division
Office of Water, Office of Science and Technology
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Phone (202) 566-0740
E-mail: nappier.sharon@epa.gov

ALTERNATE WACOR:

Shamima Akhter (Mail Code 4304T)
Phone (202) 566-1341
E-mail: akhter.shamima@epa.gov

PERIOD OF PERFORMANCE: Date of Issuance through June 30, 2020

CONTRACTOR PWS: 3.1, 3.3, 3.4, 3.6, 3.8

****Note: No Confidential Business Information data will be needed in the course of this work assignment.**

BACKGROUND:

In 2012, the Environmental Protection Agency (EPA) published Recreational Water Quality Criteria (RWQC) to protect the public from exposure to pathogens in waters designated for primary contact recreational uses. These criteria included an analysis of research, including studies evaluating the association between illness and fecal contamination in these waters. The 2012 RWQC provide two sets of numeric concentration thresholds based on the use of two bacterial indicators, *E. coli* and enterococci. Illness rates upon which these recommendations are based include the use of the National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) study and epidemiological studies used to support the 1986 Ambient Water Quality Criteria.

The Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000 requires that EPA review and as necessary revise recreational water quality criteria not later than five years after the date of publication. EPA published the first five-year review in 2017 and is now completing analyses prioritized in the review

(<https://www.epa.gov/sites/production/files/2018-05/documents/2017-5year-review-rwqc.pdf>; see Executive Summary).

This work assignment (WA) will direct follow-up analyses outlined in the published 5-year review effort. Specifically, EPA is interested in: 1) using epidemiological and quantitative microbial risk assessment (QMRA) methods to identify if there are differential risks to children, as compared to the general population, which could include re-evaluating *Enterococcus* spp. qPCR data; 2) evaluating paired microbial indicator data to establish alternative indicator and/or analytical method action values for use in ambient waters; and 3) evaluating risks associated with antimicrobial resistance (AMR) in ambient waters.

QUALITY ASSURANCE

The tasks 2 and 3 in this work assignment require the use of existing data and application of existing, peer reviewed models. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the Agency approved ICF March 2017 Programmatic Quality Assurance Project Plan (pQAPP) for Collection, Use, and Analysis (including Model Application) of Existing Data in order to assure the quality of the data used under this work assignment. The scope of the March 2017 pQAPP covers existing data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The contractor shall comply with the March 2007 EPA approved pQAPP. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved pQAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a work assignment-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the Quality Assurance and Quality Control (QA/QC) procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

TASKS:

Task 1 - Work plan and monthly progress reports

Task 1.1 Work Plan

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WACOR via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2 Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines (IQG) (www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information). The contractor shall complete the OW IQG Checklist as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the OW IQG checklist. The WACOR will provide the checklist to the contractor. At the end of the work assignment, the contractor shall provide a memorandum describing how the planned product(s) developed meet the requirements of the OW's IQG checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this work assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report.

Task 2 – Epidemiological and QMRA Analyses

Some recent studies identified in the 2017 Review of the 2012 RWQC suggest that children may ingest more water while recreating in ambient waters. This task will evaluate if children are at a higher risk of gastrointestinal illness during primary contact recreation. The contractor shall use epidemiological and quantitative microbial risk assessment (QMRA) methods to identify if there are differential risks to children, as compared to the general population. This effort may include re-evaluating *Enterococcus* spp. qPCR data and/or evaluating specific “high-risk” fecal sources, such as effluent-dominated waters.

Task 2.1 *Report of Epidemiological and QMRA Analyses*

The contractor shall collate the results and generate a publication manuscript to be submitted to journal for peer-review. EPA anticipates there will be several internal reviews of both the EPA report and manuscript prior to publication. The Contractor shall revise the reports based on comments received from EPA. Additional analyses may be needed based on the comments received. The contractor shall also be responsible for responding to reviewer comments and completing final edits.

Travel: Local travel is anticipated for this task. No contractor travel outside of the Washington, D.C. metro area is required.

Task 3 – Alternative Indictors and Methods

As stated in the 2012 RWQC, EPA anticipates that scientific advancements will provide new technologies for enumerating fecal pathogens or fecal indicator bacteria (FIB). New technologies may provide alternative ways to address methodological considerations, such as rapidity, sensitivity, specificity, and method performance. As new or alternative indicator and/or enumeration method combinations are developed, states may want to consider using them to develop alternative criteria for adoption in WQS. evaluating paired microbial indicator data to establish alternative indicator and/or analytical method action values for use in ambient waters.

As water quality data over one or more recreational seasons for the indicator/method recommended in the 2012 RWQC and a proposed alternative indicator/method combination become available, the contractor shall support the development of an action value equivalent to the 2012 RWQC values. Outputs for this task include, but are not limited to statistical analyses, excel tools, white papers, briefings, and peer-reviewed publications.

Travel: Local travel is anticipated for this task. No contractor travel outside of the Washington, D.C. metro area is required.

Task 4 – Antimicrobial Resistance (AMR)

The complex issue of antimicrobial resistance is becoming of increasing interest, creating a demand for more data to both inform our understanding of the forces driving this resistance and the actions needed to preserve bacterial susceptibility to our first-line medications. There is an increasing body of literature available on the environmental occurrence of AMR and potential exposure in recreational waters. To develop a more complete picture regarding the threat and risks associated with antibiotic resistance, research is needed to better understand the role the environment plays in transferring AMR to primary contact recreators.

As part of this task, the contractor shall collect information on 1) the occurrence of AMR in environmental waters, wastewater influent/effluents, and other potential reservoirs; and 2) the removal of AMR by various unit treatment technologies and disinfectants. Using this information and epidemiological and QMRA tools, the contractor shall assist in characterizing the potential associated public health risks associated with AMR and primary contact recreational, as well as identify possible mitigation strategies to prevent the spread of AMR.

Task 4.1 *Report of AMR Information and Analyses*

The contractor shall collate the results and generate a publication manuscript to be submitted to journal for peer-review. EPA anticipates there will be several internal reviews of both the EPA report and manuscript prior to publication. The contractor shall revise the reports based on comments received from the WACOR. Additional analyses may be needed based on the comments received. The contractor shall also be responsible for responding to reviewer comments and completing final edits.

Task 5 - General Project Support

The contractor shall, based on technical direction given by the WACOR, provide support in preparing interim project updates and other materials for internal and external audiences. Updates and other support materials may include, but are not limited to, short briefing documents, assistance with inclusion of text and results into white papers and PowerPoint presentations. The contractor may also be requested to participate in and/or conduct briefings. A weekly update call with the WACOR will be required for this work assignment, as needed.

Some meetings may require contractor support and/or attendance for note-taking, presentations, and/or meeting preparation materials. Details on travel dates and locations, for up to two trips, will be provided by the WACOR through technical direction, as further information becomes available.

Travel: Travel may be needed as deemed necessary by the WACOR.

Knowledge and Skills Required: The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting microbial analyses in the laboratory and have advanced credentials in environmental microbiology. The contractor shall be familiar with viral, protozoan, and bacterial indicators and pathogens, microbiological analytical methods (including molecular techniques), biostatistics, environmental engineering, and EPA's 2012 Recreational Water Quality Criteria. The contractor shall be familiar with the interpretation of indicator and pathogen monitoring results and how those results are related to risk estimates and public health protection.

General Requirements of the Work Assignment and Schedule:

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be issued through written technical direction from the WACOR.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.

Final Documents: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

Milestone/Deliverable Table

| Task | Task # | Milestones and Due Dates |
|--|---------------|---------------------------------|
| Task 1: Work plan, monthly progress reports and quality assurance | | |
| Workplan | 1.1 | Per contract requirements |

| | | |
|---|-----|--|
| Information Quality Guidelines | 1.2 | Discuss with WACOR within 20 calendar days after receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials). |
| Task 2: Epidemiological and QMRA Analyses | | Initial planning meeting to be held within 5 calendar days after receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed. |
| Peer-reviewed Publication of the Molecular Methods Analysis | 2.1 | <p>Unless specified by the WACOR, the schedule for the manuscript deliverables is as follows (please note that not all draft deliverable milestones will apply to all deliverables):</p> <p>Manuscript: Draft for Mgmt review – 2 weeks after receiving WACOR comments; Final – 1 week after receiving EPA Mgmt comments and approval.</p> <p>Peer-review: Response to comments – within 1 week of receiving journal comments.</p> |
| Task 3: Alternative Indictors and Methods | | TBD – as data become available |
| Paired data analyses associated with alternative indicators and methods | | TBD |
| Task 4: Antimicrobial Resistance | | Initial planning meeting to be held within 5 calendar days after receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed. |
| Peer-reviewed Publication of the Molecular Methods Analysis | 4.1 | <p>Unless specified by the WACOR, the schedule for the manuscript deliverables is as follows (please note that not all draft deliverable milestones will apply to all deliverables):</p> <p>Manuscript: Draft for Mgmt review – 2 weeks after receiving WACOR comments; Final – 1 week after receiving EPA Mgmt comments and approval.</p> <p>Peer-review: Response to comments – within 1 week of receiving journal comments.</p> |
| Task 5: General Project Support | | TBD |

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| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 3-07 | | | | |
| | | | | | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | | |
| Contract Number EP-C-16-011 | | | Contract Period 11/01/2016 To 06/30/2020 Base Option Period Number 3 | | | Title of Work Assignment/SF Site Name Lit Searches for Various DBPs | | | | |
| Contractor ICF Incorporated, L.L.C. | | | | | Specify Section and paragraph of Contract SOW see PWS | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 07/01/2019 To 06/30/2020 | | | | |
| Comments: Immediate Start Authorized | | | | | | | | | | |
| <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund | | | | | | | | | | |
| SFO <input type="checkbox"/> Note: To report additional accounting and appropriations date use EPA Form 1900-69A. (Max 2) | | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) | (Cents) | Site/Project (Max 8) | Cost Org/Code |
| 1 | | | | | | | | | | |
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| Authorized Work Assignment Ceiling | | | | | | | | | | |
| Contract Period: | | Cost/Fee: | | | | LOE: 0 | | | | |
| 11/01/2016 To 06/30/2020 | | | | | | | | | | |
| This Action: | | | | | | 380 | | | | |
| | | | | | | | | | | |
| Total: | | | | | | 380 | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | | |
| Contractor WP Dated: | | | | Cost/Fee | | | LOE: | | | |
| | | | | | | | | | | |
| Cumulative Approved: | | | | Cost/Fee | | | LOE: | | | |
| | | | | | | | | | | |
| Work Assignment Manager Name Melanie Young | | | | | | | Branch/Mail Code: | | | |
| <div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between;">(Signature)(Date)</div> | | | | | | | Phone Number: 202-250-8817 | | | |
| | | | | | | | FAX Number: | | | |
| Project Officer Name Shirley Harrison | | | | | | | Branch/Mail Code: | | | |
| <div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between;">(Signature)(Date)</div> | | | | | | | Phone Number: 202-566-1107 | | | |
| | | | | | | | FAX Number: | | | |
| Other Agency Official Name Shirley Harrison | | | | | | | Branch/Mail Code: | | | |
| <div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between;">(Signature)(Date)</div> | | | | | | | Phone Number: 202-566-1107 | | | |
| | | | | | | | FAX Number: | | | |
| Contracting Official Name Kathleen Rechenberg | | | | | | | Branch/Mail Code: | | | |
| <div style="border-bottom: 1px solid black; width: 100%;"></div> <div style="display: flex; justify-content: space-between;">(Signature)(Date)</div> | | | | | | | Phone Number: 513-487-2853 | | | |
| | | | | | | | FAX Number: | | | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-16-011
WORK ASSIGNMENT #3-07**

TITLE: Literature Searches for Various Disinfection Byproducts

WORK ASSIGNMENT CONTRACTING OFFICER'S REPRESENTATIVE (WACOR)

Melanie Young (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division (HECD)
U.S. Environmental Protection Agency (USEPA)
1200 Pennsylvania Avenue NW
Washington DC, 20460
Telephone #:202-250-8817 Fax #: 202- 566-1140
E-mail address: young.melanie@epa.gov

ALTERNATE WACOR: Jamie Strong (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division (HECD)
United States Environmental Protection Agency (USEPA)
1200 Pennsylvania Avenue, NW
Washington DC, 20460
Telephone #:202-566-0056 Fax#: 202- 566-1140
E-mail address: strong.jamie@epa.gov

LOE Hours: 380

PERIOD OF PERFORMANCE: July 1, 2019 through June 30, 2020

CONTRACT PWS: 2.1 thru 2.3, 2.5 thru 2.7, 2.9 and 2.10, 3.1.1, 3.1.2, 3.1.2.1, 3.1.3 thru 3.1.7, 3.1.7.1, 3.1.14, 3.1.14.1, 3.1.15 thru 3.1.17, 3.8, 4.1 thru 4.3

****Note: No Confidential Business Information data will be needed in the course of this work assignment.**

BACKGROUND: Under the Assistant Administrator for the Office of Water (OW), the Office of Science and Technology (OST) is responsible for developing sound, scientifically defensible criteria and standards under the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA) that articulate the goals and regulatory framework for restoring and maintaining the biological, chemical and physical integrity of the nation's water resources.

The Health and Ecological Criteria Division (HECD) is responsible for developing scientifically sound and defensible human health and ecological protection criteria and documentation to support the development of standards for drinking water, ambient water quality, sediment quality, bioaccumulation factors, microbiologicals, wildlife, wetlands and habitat, and sewage sludge.

Specifically, The Human Health Risk Assessment Branch (HHRAB) works closely with the Office of Ground Water and Drinking Water (OGWDW) in developing human health criteria supporting the derivation of maximum contaminant level goals (MCLGs) and health advisories for contaminants in drinking water. Additionally, HECD is responsible for processing petitions for adding substances to or removing substances from the list of conventional pollutants required by Section 304(a) of the CWA.

PURPOSE: The purpose of this work assignment is to provide technical and regulatory support services to HECD for the development of a health effects support document(s) to support potential changes to the Disinfectants/Disinfection Byproducts (DBPs) Rule as described in the Six Year Review 3 technical support document. ∴ This work assignment directly supports HECD mission to produce and publish scientifically sound, and implementable guidance and criteria to protect human health from drinking water. Specifically, this work assignment includes tasks to perform a literature search for these chemicals.

The contractor shall submit drafts of all deliverables to the WACOR for review prior to submission of the final product. These drafts shall clearly specify the methods, procedures, considerations, assumptions, relevant citations, data sources and data that support any conclusions and recommendations. The contractor shall incorporate all WACOR comments (and peer review comments, where applicable) into all final deliverables, unless otherwise agreed upon by the WACOR.

QUALITY ASSURANCE: The tasks in this work assignment require the use of existing data. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the Agency approved ICF March 2017 Programmatic Quality Assurance Project Plan (pQAPP) for Collection, Use, and Analysis (including Model Application) of Existing Data under EPA Contract EP-C-16-011 in order to assure the quality of the data used under this work assignment. The scope of the March 2017 pQAPP covers existing data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the March 2017 pQAPP for existing data. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a work assignment (WA)-specific QAPP supplement, which must be approved by the WACOR before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the Quality Assurance and Quality Control (QA/QC) procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

PERFORMANCE WORK STATEMENT (PWS):

TASK 1: Work Plan and Monthly Progress Reports

Task 1.1 Work Plan:

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WACOR via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

Task 1.2 Progress Reports

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.3 Information Quality Guidelines (IQG)

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines (www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information) and shall complete the OW IQG Checklist as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The WACOR will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this work assignment. The contractor shall provide the memo at the time they deliver the Final Summary Report. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

TASK 2: Systematic Literature Search

Task 2.1 Literature Search Strategy and Evaluation Criteria Development

The contractor shall conduct systematic literature searches by first creating a literature search strategy in accordance with the ICF March 2017 pQAPP for existing data.

Literature searches will be completed for approximately 5 additional disinfection byproducts. Under this PWS, an episode of work (aka “request”) will be initiated by written Technical Direction (TD). Each request will specify deadlines for delivering drafts and final work products. A TD initiation meeting between the contractor and the WACOR shall take place no later than one week after the TD is received.

The Health Effects Support Documents for Microcystins and Cylindrospermopsin or Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) should serve as an example for how to structure the literature search strategy (found at <https://www.epa.gov/dwstandardsregulations/drinking-water-contaminant-human-health-effects-information>). The EPA 2005 Brominated Acetic Acids drinking water criteria document should serve as an additional example for how to structure the literature search strategy (found at <https://tinyurl.com/Brominated-AA-DW-Criteria-Docu>).

Specifically, the literature searches should address all literature related to health effects in animals and humans resulting from acute, subchronic, and chronic exposure durations, and from inhalation, oral, dermal, and injection exposure studies. The contractor shall also identify data specifically useful for addressing risks to children and other susceptible populations (e.g., the elderly, nursing and pregnant women). The contractor shall also include other relevant studies such as in vitro studies related to mechanism of action; studies of absorption, distribution, metabolism, and elimination; and models useful for dose-response assessment such as dosimetry models and physiologically-based pharmacokinetic (PBPK) models. The literature searches should also address all literature related to occurrence and environmental fate (the Health Advisory documents for Microcystins and Cylindrospermopsin or PFOA and PFOS should serve as an example found at <https://www.epa.gov/dwstandardsregulations/drinking-water-contaminant-human-health-effects-information> should be used to structure the search for this information).

In addition to the traditional search engines such as PubMed and Toxline, Web of Science and other databases, the literature searches shall include searches for relevant domestic and international non-periodical literature, such as books, technical reports, monographs, and conference and symposium proceedings prepared by select committees or bodies (e.g., such as those convened by the National Academy of Sciences or the World Health Organization). Additionally, include searches of secondary sources such as Registry of Toxic Effects of Chemical Substance (RTECS), National Toxicology Program (NTP), National Cancer Institute (NCI), National Institute for Environmental Health Sciences (NIEHS), National Center for Toxicological Research (NCTR), TSCA Test Submissions (TSCATS) database, etc., for unpublished or interim research reports relevant to the subject of the search. Appropriate EPA health assessment documents, guidelines, and other secondary sources such as Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles shall also be used to identify relevant literature.

At the TD initiation meeting, the contractor and the WACOR shall discuss the elements to be included in the literature search strategy as well as the strategy to tag the literature. The contractor shall deliver the literature search strategy as a Word document, two weeks after the task initiation meeting. The WACOR will provide feedback as necessary and will instruct

the contractor when to initiate the literature searches.

Once the literature search strategy has been approved by the WACOR, the contractor shall conduct the literature searches and compile the results to develop a bibliography of the relevant literature for each chemical in bibliographic software (Endnote).

Task 2.2 Conduct Literature Searches and Provide Documentation

The contractor shall notify and discuss with the WACOR results of the database screens and summarize that information in a table. Documentation of the literature searches shall contain at a minimum search strings, results (number of citations), and date of searches. The table should outline the specific databases examined, keywords employed, number of hits, and any limits of the search. In addition, the number of relevant papers for each chemical should be identified by general category (e.g., human, animal toxicity, toxicokinetics, PBPK modeling, mechanism studies, etc). The contractor shall use the agreed upon evaluation factors and acceptance criteria to develop a list of citations that could be used to support EPA's evaluation of these contaminants under the SDWA. The contractor shall identify 1) a list of acceptable studies and 2) a list of studies that were found in the search, but is deemed insufficient. For acceptable studies, the contractor shall secure copies of the citations. This can be done through EPA's library, checking with the WACOR who may have a copy already or by other means. The contractor shall first discuss with the WACOR about any references needed. For studies deemed insufficient, the contractor shall collate abstracts only.

Task 3: Retrieval of Relevant Literature

The contractor shall retrieve all pertinent references according to ICF SOP for literature retrieval (SOP No. ICF-7006) The contractor shall first discuss with the WACOR about prioritizing the references needed. For studies deemed insufficient, the contractor shall collate abstracts only. The contractor shall communicate as necessary with the WACOR regarding difficult to obtain references and foreign language documents. EPA will make a determination as to whether or not to pursue retrieval of such documents. Task 2 deliverable, i.e., copies of relevant references, shall be provided in electronic format (generally in pdf format).

Task 4: General Support of Systematic Review

The contractor shall, based on written technical direction given by the WACOR, provide support in tagging relevant studies through Distiller and/ or in extracting data from relevant references into Health Assessment Workspace Collaborative (HAWC). A weekly update call with the WACOR will be required for this work assignment, as needed.

Task 5: General Project Support

The contractor shall, based on written technical direction given by the WACOR, provide support on specific data analyses may be required for briefings and/or communication materials. Such analyses would be based on written technical direction provided by the WACOR. These analyses are generally to support decision-making and usually have a defined scope to address specific risk management questions. Updates and other support materials may include, but are not limited to, short briefing documents, white papers and PowerPoint presentations. The WACOR may request the contractor to participate in and/or

conduct briefings. A weekly update call with the WACOR may be required for this work assignment, on an as needed basis.

Knowledge and Skills Required: The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in conducting literature searches and have advanced credentials in toxicology.

General Requirements of the Work Assignment and Schedule:

Due Dates: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.

Final Documents: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

SCHEDULE AND DELIVEARABLES

| Task | Task # | Milestones and Due Dates |
|--|--------|--|
| Task 1: Work plan, monthly progress reports and quality assurance | | |
| Workplan | 1.1 | Per contract requirement |
| Information Quality Guidelines | 1.2 | Discuss with EPA WACOR within two weeks after receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials). |
| Task 2: Systematic Literature Search | | Initial planning meeting to be held within 5 calendar days after receipt of work assignment. Subsequent meetings to be held roughly weekly, as needed. |
| Systematic Literature Search Strategy – DRAFT | 2.1 | Within 10 days of the initial planning meeting |
| Systematic Literature Search Strategy – FINAL | 2.1 | Within 5 days of receiving WACOR comments/approval |

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|---|-----|--|
| Systematic Literature Search Results-DRAFT | 2.2 | Within 10 days of receiving the FINAL WACOR approved Systematic Literature Search Strategy |
| Systematic Literature Search Results-FINAL | 2.2 | Within 5 days of receiving WACOR comments/approval |
| Task 3: Retrieval of Relevant Literature | | Within 10 days of receiving the FINAL WACOR approved Literature Search Results |
| Task 4: General Support of Systematic Review | | |
| Support tagging of literature in Distiller and/or extraction of data from relevant literature in HAWC | 4.1 | TBD |
| Task 5: General Project Support | | TBD |

Travel: No travel is anticipated under this work assignment.

| | | | | | | | | | |
|---|----------------|--|-------------------------------|---|----------------------------|---|---------------------------------|-------------------------|------------------|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 3-08 | | | |
| | | | | | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | |
| Contract Number EP-C-16-011 | | Contract Period 11/01/2016 To 06/30/2020 Base Option Period Number 3 | | Title of Work Assignment/SF Site Name Support for EPA's Site-Specific | | | | | |
| Contractor ICF Incorporated, L.L.C. | | | | Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.4, 3.6, 3.7, 3.8 | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 07/01/2019 To 06/30/2020 | | | |
| Comments: Immediate Start Authorized | | | | | | | | | |
| <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund | | | | | | | | | |
| SFO <input type="checkbox"/> Note: To report additional accounting and appropriations data use EPA Form 1900-69A. (Max 2) | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) (Cents) | Site/Project (Max 8) | Cost Org/Code |
| 1 | | | | | | | | | |
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| 5 | | | | | | | | | |
| Authorized Work Assignment Ceiling | | | | | | | | | |
| Contract Period: | | Cost/Fee: | | LOE: | | | | | |
| 11/01/2016 To 06/30/2020 | | | | | | | | | |
| This Action: | | | | | | | | | |
| Total: | | | | | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | |
| Contractor WP Dated: | | | | Cost/Fee | | LOE: | | | |
| Cumulative Approved: | | | | Cost/Fee | | LOE: | | | |
| Work Assignment Manager Name Shamima Akhter | | | | | | Branch/Mail Code: | | | |
| _____ (Signature) (Date) | | | | | | Phone Number: 202-566-1341 | | | |
| | | | | | | FAX Number: | | | |
| Project Officer Name Shirley Harrison | | | | | | Branch/Mail Code: | | | |
| _____ (Signature) (Date) | | | | | | Phone Number: 202-566-1107 | | | |
| | | | | | | FAX Number: | | | |
| Other Agency Official Name Shirley Harrison | | | | | | Branch/Mail Code: | | | |
| _____ (Signature) (Date) | | | | | | Phone Number: 202-566-1107 | | | |
| | | | | | | FAX Number: | | | |
| Contracting Official Name Kathleen Rechenberg | | | | | | Branch/Mail Code: | | | |
| _____ (Signature) (Date) | | | | | | Phone Number: 513-487-2853 | | | |
| | | | | | | FAX Number: | | | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-16-011
WORK ASSIGNMENT # 3-08**

TITLE: **Support for EPA’s Site-Specific Alternative Recreational Criteria Technical Support Materials (TSM) for Alternative Indicators and Methods**

WORK ASSIGNMENT CONTRACTING OFFICER’S REPRESENTATIVE (WACOR):

Shamima Akhter
Health and Ecological Criteria Division (Mail Code 4304T)
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1341
E-mail: akhter.shamima@epa.gov

ALTERNATE WACOR:

John Ravenscroft
Health and Ecological Criteria Division (Mail Code 4304T)
Office of Water, Office of Science and Technology
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Phone (202) 566-1101
E-mail: ravenscroft.john@epa.gov

CONTRACT PWS: 3.1, 3.3, 3.4, 3.6, 3.7, 3.8

PERIOD OF PERFORMANCE: July 1, 2019 through June 30, 2020

****Note: No Confidential Business Information data will be needed in the course of this work assignment.**

BACKGROUND:

An important goal of the Clean Water Act (CWA) is to protect and restore waters for swimming. A key component in the CWA framework for protecting and restoring waters for swimming in State adoption of Water Quality Standards (WQS) to protect swimmers from illnesses associated with “microbes” in the water. One of the EPA’s key roles is to recommend recreational water quality criteria (RWQC), under section 304(a) of the CWA, for adoption by the States. These EPA recommended criteria have been historically based on fecal matter in the water; in the 1960’s the Federal government recommended certain levels of fecal coliform as the recreational criteria, and in 1986 EPA recommended certain enterococci and *E. coli* as its new recreational criteria.

In November 2012, EPA published updated national recommended RWQC, which serve as guidelines to states to help them determine when water is safe enough for people to swim without getting sick from fecal contamination (for example, skin rash, stomach ache, fever). The

2012 RWQC provide two sets of numeric concentration thresholds based on the use of two bacterial indicators, *E. coli* and enterococci. Illness rates upon which these recommendations are based include the use of the National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) study and epidemiological studies used to support the 1986 Ambient Water Quality Criteria. At that time, EPA committed to providing technical documents to facilitate state development of site-specific alternative water quality criteria to protect swimmers from exposure to water that contains organisms that indicate the presence of fecal contamination. These technical support documents will help states develop alternative recreational criteria that take into account site-specific factors and incorporate the new and evolving science of microbial measurement.

One of the technical support documents ‘Site-Specific Alternative Criteria Technical Support Materials for Alternative Indicators and Methods’ where EPA anticipates that scientific advancements will provide new technologies for quantifying indicators of fecal contamination. These new technologies also might provide improvements over existing methods with regards to rapidity, sensitivity, specificity, and method performance for site-specific applications. As new or alternative indicator and enumeration method combinations mature, states, territories, and authorized Indian tribes might want to consider using these methods to develop site-specific water quality criteria (WQC). Information demonstrating that site-specific alternative criteria are scientifically defensible and protective of the recreational use is necessary to support new or revised water quality standards (WQS).

In December 2014, EPA has published online the first of three technical support documents and an overview document that provide information for states on flexible approaches for developing site-specific recreational water quality criteria that reflect the latest science. The document Overview of Technical Support Materials: A Guide to the Site-Specific Alternative Criteria TSM Documents is an overarching guide designed to help water quality managers evaluate their site information and choose the best technical approach for developing site-specific recreational water quality criteria. The first technical support document, Site-Specific Alternative Criteria Technical Support Materials for Alternative Indicators and Methods, describes how to evaluate and compare alternative methods for measuring microbes in water using an existing EPA-approved method. This document provides support materials for developing site-specific alternative WQC using new methods for fecal indicator detection or enumeration that EPA has not validated and issued. This document is part of a set of Technical Support Materials (TSMs) discussed in Section 6 of the 2012 Recreational Water Quality Criteria (EPA 820-F-12-058). This document applies to cases where states wish to use an alternative indicator/method at a site because it has certain advantages over the EPA-recommended methods. This document outlines the scientific information needed before an alternative indicator/method can replace the use of a recommended or approved method on a site-specific basis. States may replace the original method at sites where they have demonstrated that an alternative indicator/method has a consistent and predictable relationship with the original method. A state WQS using a different indicator organism or analytical method must be scientifically defensible and protective of the primary contact recreational use. EPA uses WQS for multiple Clean Water Act (CWA) purposes, so in the WQS submission states should discuss the application of the new WQS in the context of specific CWA purposes.

EPA anticipates a need to develop a spread sheet tool to calculate R-squared and Index of Agreement from Appendix E (EPA-820-R-14-011) where states can plug-in the data set.

QUALITY ASSURANCE:

The tasks (2 and 3) in this work assignment require the use of existing data to create a calculation work sheet. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the Agency approved ICF March 2017 Programmatic Quality Assurance Project Plan (pQAPP) for Collection, Use, and Analysis (including Model Application) of Existing Data in order to assure the quality of the data used under this work assignment. The scope of the March 2017 pQAPP covers existing data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The contractor shall comply with the EPA approved pQAPP. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the approved pQAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a work assignment (WA)-specific QAPP supplement, which must be approved by the WACOR before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the Quality Assurance and Quality Control (QA/QC) procedures for compiled data and any summaries generated in this work assignment are required when all tasks are completed.

PERFORMANCE WORK STATEMENT (PWS): The scope of work in this assignment will fall under the following task areas:

Task 1: Work plan and monthly progress reports

Task 1.1 Work Plan

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the WACOR via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

Task 1.2 Information Quality Guidelines

The contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents

<http://www.epa.gov/quality/informationguidelines/>. The WACOR will provide the checklist to the contractor. The contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The contractor shall provide the memo at the time it delivers the Final Summary Report. As requested by the WACOR, the contractor shall have a teleconference with the WACOR to discuss the Guidelines and the contractor's role in completing the checklist.

Task 2: Spreadsheet Tool for Calculating Index of Agreement and R-squared

The contractor shall develop an Excel Spreadsheet based on Appendix E (Site Specific Alternative Recreational Criteria Technical Support Material for Alternative Indicators and Methods for calculating Index of Agreement and R-squared (EPA-820-R-14-011)). The contractor shall include: 1) user notes – tab in spreadsheet on how to use it; and 2) Clear format – so user knows which cells to populate. The contractor shall provide clear and consistent format of the spreadsheet.

The contractor shall enhance the tool to allow users the option of either (i) saving an analysis in a new worksheet as part of the existing workbook or (ii) saving the analysis as a separate new workbook. With the former option, users will be able to save multiple analyses within the same workbook. If an analysis is saved within the existing workbook, the new worksheet should contain all inputs, outputs, figures, and data documentation related to that analysis. This additional functionality will require modification of the underlying Visual Basic macros to generate new interactive screens and the modification of existing macros to facilitate the generation of a new worksheet containing all the required analysis elements copied from the tool operation tab.

In addition, the contractor shall enhance the tool to allow users to optionally specify an EPA-approved indicator (X-axis indicator) threshold that will appear on the figure as a straight dashed line intercepting the X-axis at the specified threshold. If no threshold is specified, no line will appear. This additional functionality will require modification of the underlying Visual macros and sheet-based commands to achieve the required objective.

The contractor shall provide the WACOR the draft spreadsheet tool for EPA internal revision. Upon receiving the WACOR comments, the contractor shall incorporate all EPA comments to the draft document. The contractor shall coordinate all aspects of the spreadsheet tool with the WACOR. **The draft deliverable is now under EPA review. The contractor shall address all EPA comments to the draft deliverable upon receiving from the WACOR. The contractor shall provide the revised spreadsheet tool to the WACOR for review and for any additional comments.**

Task 3: Spreadsheet Demonstration

The contractor shall provide user support in coordination with the WACOR. The contractor shall provide a one-hour training to teach users how to use the spreadsheet. The contractor shall provide a draft presentation of the training to the WACOR for EPA review. The contractor shall address all the WACOR comments. After addressing all EPA comments, the contractor shall assist the WACOR with the webinar training for the public.

Task 4 - General Project Support

The contractor shall, based on technical direction given by the WACOR, provide support in preparing interim project updates and other materials for internal and external audiences. Updates and other support materials may include, but are not limited to, short briefing documents, PowerPoint presentations, conference posters, and internal EPA communication package. The contractors may also be requested to participate in and/or conduct briefings. A weekly update call with the WACOR will be required for this work assignment, as needed. Some meetings may require contractor support and/or attendance for note-taking, presentations, and/or meeting preparation materials.

TRAVEL: Local travel is anticipated under this work assignment. No contractor travel outside of the Washington, D.C. metro area is required.

KNOWLEDGE AND SKILLS REQUIRED:

The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The contractor shall have practical experience in statistical methods and have analysis and have advanced credentials in environmental microbiology. The contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques) water monitoring, applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development

General Requirements of the Work Assignment and Schedule:

The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR in writing, with the Contracting Officer (CO) copied, at the first sign of said delay. A revised schedule will then be revised by the WACOR and provided to the contractor by the CO.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.

Final Documents: The contractor shall submit final documents both electronically and in hardcopy to WACOR.

MILESTONES/DELIVERABLES TABLE:

| Task | Milestone | Date due |
|-------------|---|---|
| 1 | Work plan, monthly progress reports and quality assurance | Per contract requirements |
| 1.1 | Work Plan | Per contract requirements |
| 1.2 | Information Quality Guidelines | Discuss with WACOR within 20 calendar days after receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials). |
| 2 | Spreadsheet Tool for Calculating Index of Agreement and R-squared | No later than 5/31/2020 |
| 3 | Spreadsheet Demonstration | Due as requested by the WACOR via written technical direction |
| 4 | General Project Support | Due as requested by the WACOR via written technical direction |

| | | | | | | | | | |
|---|----------------|----------------------|---|---|----------------------------|---|---------------------------------|-------------------------|------------------|
| EPA United States Environmental Protection Agency Washington, DC 20460 Work Assignment | | | | | | Work Assignment Number 3-09 | | | |
| | | | | | | <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number: | | | |
| Contract Number EP-C-16-011 | | | Contract Period 11/01/2016 To 06/30/2020 Base Option Period Number 3 | | | Title of Work Assignment/SF Site Name Technical Support to Develop t | | | |
| Contractor ICF Incorporated, L.L.C. | | | | Specify Section and paragraph of Contract SOW 2.1 thru 2.5, 2.7, 2.9, 2.12, 3.1.1 thru 3.1.17... | | | | | |
| Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval | | | | | | Period of Performance From 07/01/2019 To 06/30/2020 | | | |
| Comments: Immediate Start Authorized | | | | | | | | | |
| <input type="checkbox"/> Superfund Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund | | | | | | | | | |
| SFO <input type="checkbox"/> (Max 2) Note: To report additional accounting and appropriations date use EPA Form 1900-69A. | | | | | | | | | |
| Line | DCN (Max 6) | Budget/FY (Max 4) | Appropriation Code (Max 6) | Budget Org/Code (Max 7) | Program Element (Max 9) | Object Class (Max 4) | Amount (Dollars) (Cents) | Site/Project (Max 8) | Cost Org/Code |
| 1 | | | | | | | | | |
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| Authorized Work Assignment Ceiling | | | | | | | | | |
| Contract Period: | | Cost/Fee: | | LOE: | | | | | |
| 11/01/2016 To 06/30/2020 | | | | 0 | | | | | |
| This Action: | | | | 235 | | | | | |
| Total: | | | | 235 | | | | | |
| Work Plan / Cost Estimate Approvals | | | | | | | | | |
| Contractor WP Dated: | | | | Cost/Fee | | LOE: | | | |
| Cumulative Approved: | | | | Cost/Fee | | LOE: | | | |
| Work Assignment Manager Name Lesley Vazquez-Coriano <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: Phone Number: 202-566-1125 FAX Number: | | | |
| Project Officer Name Shirley Harrison <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: Phone Number: 202-566-1107 FAX Number: | | | |
| Other Agency Official Name Shirley Harrison <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: Phone Number: 202-566-1107 FAX Number: | | | |
| Contracting Official Name Kathleen Rechenberg <div style="display: flex; justify-content: space-between;"> <div>_____ (Signature)</div> <div>_____ (Date)</div> </div> | | | | | | Branch/Mail Code: Phone Number: 513-487-2853 FAX Number: | | | |

**PERFORMANCE WORK STATEMENT
ICF CONTRACT EP-C-16-011
WORK ASSIGNMENT #3-09**

TITLE: Technical Support to Develop the Health Effects Support Document and Human Health Ambient Water Quality Criteria for Saxitoxins

WORK ASSIGNMENT CONTRACTING OFFICER'S REPRESENTATIVE (WACOR):

Lesley D'Anglada (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division (HECD)
United States Environmental Protection Agency (USEPA)
1200 Pennsylvania Avenue NW
Washington DC, 20460
Telephone #:202-566-1125 FAX #: 202- 566-1140
E-mail- danglada.lesley@epa.gov

ALTERNATE WACOR: Sharon Nappier (Mail Code 4304T)
Office of Water, Office of Science and Technology
Health and Ecological Criteria Division (HECD)
United States Environmental Protection Agency (USEPA)
1200 Pennsylvania Avenue NW
Washington DC, 20460
Telephone #: 202-566-0740 FAX #: 202- 566-1140
E-mail- nappier.sharon@epa.gov

Contract PWS: 2.1 thru 2.5, 2.7, 2.9 and 2.12, 3.1.1 thru 3.1.17 (entire section), 3.3.1, 3.3.4., 3.3.5., 3.4, 3.8.2, 4.1 thru 4.3

PERIOD OF PERFORMANCE: July 1, 2019 through June 30, 2020

****Note: No Confidential Business Information data will be needed in the course of this work assignment.**

BACKGROUND:

Under the Assistant Administrator for the Office of Water (OW), the Office of Science and Technology (OST) is responsible for developing sound, scientifically defensible criteria and standards under the Clean Water Act (CWA) and the Safe Drinking Water Act (SDWA) that articulate the goals and regulatory framework for restoring and maintaining the biological, chemical and physical integrity of the nation's water resources.

The Health and Ecological Criteria Division (HECD) is responsible for developing scientifically sound and defensible human health and ecological protection criteria and documentation to support the development of standards for drinking water, ambient water quality, sediment quality, bioaccumulation factors, microbiologicals, wildlife, wetlands and habitat, and sewage

sludge. Specifically, HECD works closely with the Office of Ground Water and Drinking Water (OGWDW) in developing human health criteria supporting the derivation of maximum contaminant level goals (MCLGs) and health advisories for contaminants in drinking water. Additionally, HECD is responsible for developing *Ambient Water Quality Criteria for the Protection of Human Health* under Section 304(a) of the CWA to protect designated uses in ambient waters. For chemicals that bioaccumulate, water quality criteria also describe the maximum advisable concentration of a chemical in freshwater and estuarine fish and shellfish tissue to protect consumers of fish and shellfish among the general population.

Previously the contractor's support started under Work Assignment 1-09 of this contract to perform a literature search and selection of relevant literature for saxitoxins. This work assignment directly supports HECD mission to produce and publish scientifically sound, and implementable guidance and criteria to protect human health from drinking water. Specifically, this work assignment included tasks for ICF to conduct a comprehensive literature review and deliver the searchers and other documents to EPA.

PURPOSE:

The purpose of this work assignment is to do summary write-ups of selected studies provided by the WACOR on health effects from oral exposure to saxitoxins in water. The contractor shall provide technical support to the WACOR, within the approved level of effort (LOE), in the task areas outlined below. This work assignment covers the various aspects needed to complete support of the development of the Hazard Identification Section which include a description of human effects from epidemiological, case studies, and animal toxicity studies, for the Health Effects Support Document (HESD) for Saxitoxins (SXT). The HESD for SXT document presents information, including toxicology and epidemiology data, for the cyanobacterial toxin saxitoxins to be considered in the development of a Drinking Water Health Advisory (DWHA) and the Human Health Ambient Water Quality Criteria.

QUALITY ASSURANCE:

The tasks in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall follow the approved ICF March 2017 Programmatic QAPP (pQAPP) to assure the quality of the data used under this work assignment. The scope of the March 2017 QAPP covers secondary data review, existing peer reviewed model application, but does not anticipate data generation or acquisition.

The contractor shall comply with this EPA approved QAPP. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1. The contractor shall discuss with the WACOR if any of the specific work assignment tasks are not readily covered under the QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a work assignment (WA)-specific QAPP supplement, which must be approved by the EPA before activities covered by the additional QA language begin under this work assignment. A final QA statement detailing the Quality Assurance and Quality Control (QA/QC) procedures

for compiled data and any summaries generated in this work assignment is required when all tasks are completed.

PERFORMANCE WORK STATEMENT (PWS):

TASK 1: Support for Developing the Hazard Identification Section for the Health Effects Support Document for Saxitoxins

Task 1.1 Draft Summaries for Human Health Data for EPA's Review

The contractor shall use the references, including peer-reviewed articles and government assessments, provided by the WACOR to draft summaries of the studies health effects findings. The contractor shall submit the draft summaries to the WACOR for review. This document will be delivered electronically in Microsoft Word format (or current Agency format), to the WACOR and it should be free of any technical, typographical or editorial errors.

Task 1.2 Response to Comments and Development of Final Summaries of Human Health Data

Once the WACOR provides the comments on the Draft health studies summaries, the contractor shall revise the draft summaries and shall make technical and editorial edits in response to the WACOR technical directions. The contractor shall develop a tracking sheet and notations on the excerpts to track draft and review status.

TASK 2: General Project Support

Task 2.1 Conference Calls

The contractor shall schedule update calls with the WACOR and meet as directed.

Knowledge and Skills Required: The contractor shall have practical experience and knowledge in toxicology and epidemiology. The contractor shall have expertise in preparing the materials and be knowledgeable with the various fields of discipline discussed in this work assignment.

General Requirements of the Work Assignment and Schedule:

Due Dates: The contractor shall provide due dates that are mutually acceptable with the WACOR. The contractor shall notify the WACOR in advance, if a due date will not be met and request a revised date.

Delays: The contractor shall make every effort to ensure there are no contractor-caused delays. If a delay is inevitable, it is the contractor's responsibility to notify the WACOR at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. The WACOR will provide comments on draft submissions prior to submission of final documents.

Final Documents: The contractor shall submit final documents both electronically to WACOR.

SCHEDULE AND DELIVEARABLES:

| Task | Task # | Milestones and Due Dates |
|---|--------|--|
| <u>TASK 1: Support for Developing the Hazard Identification Section for the Health Effects Support Document for Saxitoxins</u> | | |
| Receive Human Health references form the WACOR | 1.1 | Within 2 weeks after Work Plan approval. |
| Draft Summaries of Human Health Studies Data for EPA Review | 1.1 | Within 10 weeks after studies are provided by the WACOR. |
| Response to Comments and development of Final draft summaries | 1.2 | Within 2 weeks of receiving EPA comments. |
| Final Toxicokinetics Section | 1.2 | Within 2 weeks of providing response to comments to the WACOR. |
| Task 2: General Project Support | 2.1 | Conference Calls – as needed |

Travel: Most communications related to this work assignment can be effectively accomplished via telephone, email, and mail deliveries. No travel outside of the Washington, D.C. metro area is anticipated, however, local travel may happen if needed.